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SELECTED ASPECTS OF THE CONTROL OF TOXIC SUBSTANCES (A COMPILATION OF SPEECHES), BY THE MEMBERS OF THE STAFF OF THE OFFICE OF TOXIC SUBSTANCES

Environmental Protection Agency

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This collection of speeches by members of the staff of the Office of Toxic Substances in large measure reflects the evolution of the interests, policies, and programs of the Office during the last several years. Hopefully this collection, and particularly the more recent items, will be helpful to specialists and persons concerned with governmental policies and objectives in this area.

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(A Compilation of Speeches)

by the

MEMBERS OF THE STAFF OF THE
OFFICE OF TOXIC SUBSTANCES

U.S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 1976

PREFACE

This collection of speeches by members of the staff of the Office of Toxic Substances, together with a previously published compilation of speeches by the Director (A Framework for the Control of Toxic Substances, Office of Toxic Substances, April 1975), in large measure reflects the evolution of the interests, policies, and programs of the Office during the last several years. Hopefully this collection, and particularly the more recent items, will be helpful to specialists and persons concerned with governmental policies and objectives in this area.

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CHEMICALS AND ENVIRONMENTAL CONCERNS

Delivered by
Glenn E. Schweitzer
Director, Office of Toxic Substances

to the
43rd Annual Meeting of the Adhesives Manufacturers
Association
Lake of the Ozarks, MO - May 13, 1976

A National Perspective in an Election Year

Every four years a Presidential election fills the air with promises, hopes, and frustrations. While called rhetoric, the debates surrounding the election process nevertheless force us to consider at least in a very cursory way many of the issues of the day and to reflect on some of our underlying values. For at least a moment we step back from the trees and take a broader look at the forest.

This year is no different. The ever present issues of defense spending, tax inequities, medical care, and educational deficiencies blanket the front pages of our newspapers. Permeating every discussion is concern over the size of the Governmental bureaucracy and the constant rise in the federal budget. Political responses range from vague promises to reduce Governmental control over our spending habits and our life style to very specific legislative proposals that require termination and reauthorization of all Governmental programs every four years -- an approach so artfully labelled "sunset".

One thread that seems to run through all the political statements over the last few months is the need for reasonable accommodation of a variety of conflicting interests in every Governmental endeavor. All must benefit from new approaches while no one gives up any current advantages. Social equality must not be jeopardized by economic progress. Economic opportunities for all must not stifle the economic incentives that inspire a few.

In no area are the inherent conflicts of interest and the competition among value systems more obvious than in our efforts to balance environmental concerns with economic growth and with energy conservation. We long ago abandoned the idea that environmental control is free. The appropriate size of the price tag is now the issue. Unfortunately, it is too easy simply to attribute the loss of jobs and the rising cost of living to environmental controls and to generalize from local impacts to a comparable national problem. Indeed, politicians at all levels of Government are using the environmental control issue to serve their particular interests. Meanwhile, the very serious and very complex environmental trade-offs are seldom debated in a sound and unemotional manner.

Recent Environmental Trends

During the past five years there has been some progress in slowing the rate of pollution -- in beginning to clean up some of our rivers and to prevent the continued growth of air pollution in some of our cities. At the same time, as our population and our economy continue to expand and as the potential for pollution increases, progress clearly is not as rapid as envisioned several years ago. Whether we underestimated the magnitude and complexity of the tasks, whether the parties directly impacted by requirements to slow pollution are rebelling, or whether the momentum of the environmental movement has been blunted through the long and tortuous routes of legal machinations accompanying regulation, it is clear that we have a long way to go in preserving our environment for the generations of the future.

At the national level, our timetables for controlling automobile exhausts and for controlling point source discharges are slipping, but we have not abandoned our environmental goals in any area. Unfortunately, I cannot think of any area where we have advanced our timetables, but hopefully with the recovery of the economy, some of the difficulties of the last several years may be behind us.

Meanwhile, the movement for regulatory reform has picked up a great deal of momentum in the Congress, in the Executive Branch, and, of course, in business circles. It has been long accepted that Governmental regulation is essential to compensate for inequities attendant to a free marketplace. However, the ever increasing number of regulatory activities at the Federal, state, and local levels have raised genuine concerns as to the appropriate role of Government in controlling almost every thread of the fabric of our economic and social system. Regulatory reform initially was spurred by concerns over economic imbalances resulting from regulation and over allegations of economic favoritism among the regulated parties. More recently the concerns underlying the move for regulatory reform are encompassing the social as well as economic inequities that may accompany individual regulatory actions.

While the debate begins with the philosophical questions as to the most appropriate Governmental role in society, regulatory reform advocates very quickly focus on specific regulatory decisions which do not coincide with their views. Relatively little time is spent addressing the general policies which form the framework for specific regulatory decisions. Let me cite two examples where I think we are making progress, at least in the environmental area. First, there is now a tendency to limit and sharpen the number of regulations to prevent or correct specific types of problems rather than broad scale approaches which simply extend the net of Governmental control without concomitant impact which benefits society. Secondly, meaningful public participation in the regulatory decision-making process is becoming more and more of a reality. However, some elements of our society are at a considerable disadvantage in knowing how or having the wherewithal to participate.

There seems to be little doubt that chemical pollution in the broadest sense is and will continue to be for many years a major environmental concern. The inherent characteristics of chemical products, the contaminants associated with these products, and the chemical discharges associated with the manufacturing, processing, use, and disposal of the products have become major items of concern in Washington, in State capitals, and in the press. Our early efforts to control the gross pollution parameters (e.g., COD, BOD, TSS), to regulate food, drugs, and pesticides, and to protect the worker in the plant are recognized as important steps in addressing chemical pollution. However, these steps have not been entirely effective and indeed neglect the vast majority of the industrial chemicals which eventually find their way into the environment.

In reviewing developments during the past year in Washington, perhaps the most volatile environmental issue has been the problem of environmental carcinogens. While the frustrations of several EPA lawyers and scientists at the National Cancer Institute have provided the grist for Congressional hearings, the questions involved are far more profound than might be suggested by such superficial actions. It seems virtually impossible to disentangle scientific fact from scientific judgments and from value judgments in generalized statements about environmental carcinogens. In my view, while certain guidelines can be developed for raising the flag of concern over suspected carcinogens, regulatory actions to limit uses of such chemicals must be based on a chemical-by-chemical assessment.

Pending Legislation to Control Toxic Substances

As you are aware, for more than five years the Toxic Substances Control Act has been pending in the Congress.

The fundamental public policy issues which this legislation addresses are: Does the public have a right to know what chemicals are being manufactured, what chemicals are likely to reach the public and its ecological resources, and what are the likely effects of these chemicals on man and the ecology? Does the public have the right to participate in decisions -- which up until now have been made almost exclusively by industry -- as to whether man or the ecology should be exposed to these chemicals? The Toxic Substances Control Act would establish mechanisms for the public to exercise these rights, both directly and acting through Governmental agencies.

This legislation has four purposes:

-- To develop authoritative information about the production, use, and effects of commercial chemicals -- information that will improve regulatory decisions made by several agencies under a variety of existing laws as well as under the new legislation.

-- To anticipate and prevent environmental problems and the economic dislocations attendant to corrective actions by evaluating the risks associated with commercial chemicals prior to major commercial investments.

-- To help insure that in the regulatory decision-making process the total impact of regulations on society are taken into account, including consideration not only of environmental risks but also of impacts on the economy, business, and employment.

-- To provide institutional mechanisms for coordinating regulatory approaches to toxic chemicals being taken by a number of Governmental agencies under a variety of laws.

With regard to the status of the legislation, about six weeks ago the Senate passed one version of the legislation and the House Commerce Committee is currently considering a version which differs in some respects. I cannot predict the Congressional timetable.

Should the legislation be enacted and signed into law, as a first step EPA will undertake an intensive period of consultation with all interested parties prior to developing an implementation strategy or preparing any particular regulations. While in many areas the intent of Congress will be quite clearly spelled out in the legislation and in the Committee reports, the EPA Administrator will undoubtedly have a considerable degree of discretion in many instances. Despite a very tight implementation timetable for initial actions which will probably be specified in the law, we nevertheless feel that all interested parties should have the opportunity from the outset to make their suggestions on the most sensible implementation strategy. We estimate that the initial round of structured consultations will take about two months, although obviously consultations will continue throughout the lifetime of the legislation.

While I do not plan to trace the many twists and turns of the various bills, let me make a few comments about several provisions which we know have been of particular concern to the Adhesives Manufacturers Association. We commend your efforts in making your views known to both the executive and legislative branches, for it is important that as this proposed law makes its way through the legislative process the implications be as well understood as possible.

With regard to mixtures, the Congressional intent clearly is not to equate mixtures with chemical substances. At the same time there is recognition of the need to retain the option of considering that certain mixtures on a selective basis might indeed be of environmental concern due to the effects of individual ingredients or the combined effects of several ingredients acting in concert. Thus, mixtures presumably would not be subjected to any comprehensive requirement concerning premarket notification or annual reporting although on a case-by-case basis the Administrator could address specific mixtures which might be of particular environmental concern. There is, of course, the problem of defining what is meant by a mixture, or by a non-reactive mixture. The Japanese consider for the purposes of their premarket notification that dry mixtures are not accompanies by chemical reactions. On the other hand, they recognize that liquid mixtures often involve chemical reactions and therefore pose quite complicated legal and procedural problems.

Turning more specifically to your concerns, let me cite language in the recent Senate report on the pending legislation:

> "There are mixtures such as, adhesives, paints and inks, which can produce chemical substances upon end use. Chemical substances produced upon end use of such mixtures should not be considered new chemical substances automatically subject to the premarket notification provisions of this section. Manufacture is defined under section 3(a)(7) to mean to 'import, produce, or manufacture for commercial purposes.' These types of substances would not be covered under the premarket notification provisions because they are not manufactured for commercial purpose, per se. Similarly, minor reactions occurring incidental to the mixing process or upon storage of a mixture, such as the cross-linking of polymers, would not constitute a basis for subjecting such mixtures to the premarket notification provisions intended for new chemical substances because the resulting substances are not manufactured for commercial purpose."
>
> "Such chemical substances arising during the formulation, storage or use of such mixture should be considered as byproducts of the precursor substance or substances. The responsibility for reporting and testing such byproducts under the provisions of this legislation would then fall upon the manufacturer of the precursor substance. Of course, the Administrator may specifically subject any mixture to the premarket notification provisions."
>
> "Subsection (k) specifically exempts from the premarket notification provisions chemical substances which are manufactured or intended to be manufactured in small quantities solely for scientific experimentation or analysis or for chemical research. The Administrator is authorized to include those kinds of chemical substances when they may result in an unreasonable risk to injury to human health or the environment."

And with regard to the currently pending version of the legislation in the House:

> "The term 'mixture' means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that such term does include a combination which occurs, in whole or in part, as a result of a chemical reaction if each of the chemical substances comprising the combination is not a new chemical substance and if the combination could have been manufactured for commercial purposes without a chemical reaction in the mixing process."

In all of these areas, we anticipate that there will be relatively good guidance from the Congress. However, in preparing implementing regulations, many minor problems will undoubtedly be uncovered. It is the purpose of the two-month consultation period to identify the problems more precisely prior to proposing specific regulations.

The Longer Term Perspective

The adverse effects of chemicals in the environment are now front page news in the press and command prime time on television. While the public media may not be a good barometer of the severity of the problems facing our society, nevertheless it is a potent factor in determining future directions of governmental policy. The frequency of chemical incidents will undoubtedly continue to rise, and more and more linkages between chemicals and health and ecological problems will be identified. Furthermore, as our sampling and analytical techniques continue to become more sophisticated, more and more man-made chemicals will be found in our drinking water, in our food resources, in the air, in the water, in the soil, and in the flora and fauna. It is against this background of concern, a concern which is understandable to every citizen, that the chemical industry must face the challenges of the decades ahead.

All signs are that chemicals will continue to undergird our economy in many ways. They will provide us with the industrial and consumer products needed to maintain our standard of living. They will contribute heavily to a favorable balance of payments. They will reduce our reliance on using non-renewable resources to solve many urgent human needs.

The chemical industry is expected to increase its efforts to assess the environmental acceptability of its products. Simply complying with current regulations is not enough. Industry has a better appreciation of many of the potential problems associated with its products than does Government. Industry is expected to increase its investigations of the properties of its products, the byproducts of its manufacturing processes, and the impact of these products and byproducts on the worker, on neighborhood residents, and on the surrounding ecological resources. The major share of the responsibility for needed epidemiological investigations, for toxicological studies, and for fenceline monitoring rests with industry. The Government has an obligation to provide guidance concerning acceptable standards and to insure the adequacy and validity of industrial investigations. However, the initiation and conduct of the investigations are the responsibility of that segment of society that derives direct economic gain from producing those chemicals which are of concern.

I am hopeful that in the years ahead, industry will more actively seize this responsibility and reduce the necessity for large numbers of Governmental regulations. Seldom are regulations promulgated when industry itself has recognized the problem and taken corrective actions. Indeed, industry initiative is the keystone to minimizing unnecessary Governmental interventions that can have a disruptive effect on normal business patterns.

INTERNATIONAL DIMENSIONS OF REGULATORY DECISIONS

Delivered by
Glenn E. Schweitzer
Director, Office of Toxic Substances

to the
National Conference of American Society for
Public Administration
Washington, DC -- April 20, 1976

The Growing Array of Regulatory Activities

The realities of the need for the meshing of international and domestic considerations in Governmental decision-making are not difficult to uncover in the regulatory area. At the same time, appropriate methodologies and practical approaches for clarifying and integrating such considerations are far more elusive. Seldom are the issues as sharply defined as was the case with the Concorde, and even then many of the technical and economic factors were far from clear.

In response to the growing array of regulatory activities, particularly at the Federal level, regulatory reform has become a popular theme within the Congress, the Executive Branch, and the business community. While regulatory intervention by Government has in principle long been condoned as necessary to help correct inequities resulting from a free marketplace, the spread of regulations continually raises concerns over the appropriate role of Government -- a role that impacts, and often decisively, on the inner fabric of our economic and social systems.

The calls for regulatory reform have often related to domestic economic dislocations and charges of economic favoritism which result from regulatory activities, and more recently to social imbalances that accompany regulation. Regulatory reform is having an impact. For example, we are becoming increasingly sensitive to the need for more sharply focused regulatory actions to prevent and redress significant distortions in national priorities resulting from a free marketplace, rather than fuzzy, broad-scale approaches that simply compound our concerns. Also, we welcome recent recognition of the rightful role of the public to participate in a more meaningful way in the decision-making process. However, we are only beginning to appreciate how global interdependence is bringing an increasingly important aspect to regulatory decisions.

The international dimension certainly adds a layer of complication to an already complex web of interrelated regulatory, economic, and social objectives attendant to policies and decisions of regulatory agencies; for this dimension is fraught with legal, financial, political, and even scientific diversities. Nevertheless, responsible Governmental regulatory actions on the domestic front should re-

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flect international considerations if the broadest aspects of our national interest are to be served, and indeed, in some instances, if domestic regulations are to achieve their intended purposes.

There are many types of regulations. This discussion will be limited to Federal regulatory actions intended to protect human health or ecological resources from harmful chemical products or contaminants. Such actions are largely within the purview of the Environmental Protection Agency, Food and Drug Administration, Department of Labor, Department of Transportation, Department of Interior, and Consumer Product Safety Commission. Of course, a number of research organizations of many Federal agencies support these activities.

The Role of International Cooperation

Serious cooperation in the development of international approaches to health and sanitation standards for international travelers and for shipments of perishable goods across borders goes back many decdes. Many United Nations bodies and other international organizations are involved.

Similarly, international collaboration in research has long been a way of life in the scientific community. International references are frequently cited in the scientific documentation supporting regulatory actions, and this distribution of the research load among nations seems to be having some payoff for the United States. Also, in the field of toxic chemicals, harmful incidents in one country have on occasion alerted other nations to the need for prompt preventive or corrective actions, such as in the cases of mercury, cadmium, hexachlorobenzene, and thalidomide.

In addition to the benefits of relevant research results and problem anticipation resulting from international cooperation, several other considerations are often cited in justifying collaboration. These include the moral responsibility of the world's largest polluter to share advanced scientific and technological expertise, the likelihood that U.S. economic exports will follow in the wake of exports of U.S. science and technology, and the support of political objectives through technological collaboration on a bilateral or multilateral basis. In any event, the United States is and will undoubtedly continue to be committed to a wide range of formal and informal cooperative efforts through Governmental and non-Governmental channels.

Sometimes, an international approach is essential if regulations are to be meaningful. For example, should limitations on certain types of fluorocarbon discharges to protect the ozone layer be warranted, concerted international actions would seem critical, given the widespread manufacture and environmental discharges of these chemicals. Similarly, the need for multinational action to help prevent contamination of the oceans and Great Lakes by widely used and persistent chemicals is reflected in a variety of international arrangements. An interesting example of the international aspects of regulations has been the need to insure the availability of unleaded gasoline in Mexico and other countries for US tourists driving cars equipped with catalytic converters. And of course Europe, and to a lesser extent some US border communities, have long been seized with the international aspects of air pollution.

Concern has been voiced over competitive imbalances, and related effects for trading patterns, resulting from inconsistent environmental standards among nations. However, authoritative evidence is in short supply as to the real world effects of the differences of stringency in environmental controls in different countries. The developing countries contend, at least within the UN Conference on Trade and Development, that environmental decisions of the developed countries could adversely affect imports from the developing countries, imports which might become environmentally unacceptable due to their inherent properties or possible contaminants. Also, while the imported product itself may not be of environmental concern, in the process of further manufacture or processing, environmental measures might be applied which could jeopardize the competitive position of the product.

International Trends in the Chemical Industry

During the past decade both the sellers and buyers of chemicals have rapidly expanded international operations. International trade in chemicals now exceeds $50 billion annually. Chemical exports contribute more than $4 billion to our balance of payments annually. U.S. companies are investing heavily abroad, financing the investments through transfer of capital from the United States, reinvestment of foreign earnings, reinvestment of depreciation reserves, and sale of securities abroad. Total foreign investments of U.S. chemical firms are now on the order of $10 billion. Foreign plants of U.S. based multinationals have had a mixed impact on U.S. exports, replacing some items but stimulating the flow of others. At the same time several foreign subsidiaries in the United States have chemical sales in this country exceeding $1 billion annually. Among the areas of particular importance to these subsidiaries are fibers, drugs, and dyes. Joint ventures and licensing arrangements further extend the international reach of many of the larger companies.

Foreign investments are stimulated by many factors, and inhibited by others. Tariff and non-tariff barriers, proximity to markets and supplies, production and labor considerations, and local political and economic trends are all central to investment decisions. Patent protection, strength of the scientific community, and available technology and engineering services are particularly important in highly innovative fields.

The impact of pollution havens on major decisions involving production facilities in the chemical industry is not clear. However, available evidence suggests that local environmental regulations are seldom a decisive factor in major investment decisions.

Once investments are in place, an international ripple effect can result from product-oriented regulatory decisions. In responding to constraints imposed on the manufacture or use of a product in one country, the concerned multinational firm would normally review its world-wide operation involving the product. One type of conclusion might be that a ban on some or all of the uses of a chemical in one country (e.g., the United States) so limits the market that production for world-wide sale is no longer profitable. Another type of conclusion might be that limitations on manufacturing can readily be overcome by importation of the chemical product.

Examples of Regulatory Impacts

The experiences of the drug industry in responding to the 1962 amendments to the Food, Drug, and Cosmetics Act are frequently cited to illustrate the impacts domestically and internationally of product regulations. One report states that since 1961, the percentage of new drugs initially introduced in the United States has slipped from over 30 to less than 10 percent of the worldwide introductions. The requirements imposed by the Food and Drug Administration (FDA) concerning approval prior to human testing and prior to clinical trials have undoubtedly had an influence on industrial decisions as to the locations for drug development activities. A second factor which may influence the location of animal experiments and clinical trials in some cases is the attention research findings of local investigators will receive in local medical journals which in turn can encourage doctors to prescribe the new drugs. A third consideration is the reticence of one Government (and particularly FDA) to accept with minimal questions research results from abroad and drug approvals by another Government. Finally, costs of R and D activities abroad may be lower.

Turning to the pesticide area, our domestic concerns over the adverse impact of DDT on ecological resources and the concurrent concerns of developing couuntries over its value to combat malaria are well known. As we accelerate our effects to re-examine other common pesticides, we are likely to be confronted with similar dilemmas. Also, as tolerances for pesticide residues which are present as food contaminants are expanded and perhaps tightened, certain imported products may be affected. Another example of immediate concern relates to ethylene dibromide, an important fumigant used by the Department of Agriculture to treat imported grain, which has been shown to be a very fast acting carcinogen at high dose levels in laboratory animals.

Recent regulatory actions by the Occupational Safety and Health Administration and by EPA directed to industrial chemicals have probably had international repercussions, both by affecting production costs and by stimulating regulatory agencies in other countries to take similar regulatory actions. Should toxic substances legislation directed to the testing and regulation of a broader range of industrial chemicals be enacted in the United States, and in other countries as well, international concerns will probably loom large in a variety of future regulatory actions. Let me cite two examples of the types of concerns which have arisen with regard to industrial chemicals.

In attempting to assess the economic impact of an air emission standard for vinyl chloride in early 1974, limited attention was given to the international aspects of possible price rises of PVC due to the costs of installing and operating the control technology required to reduce sharply the emission levels. Among the factors that were identified as potentially important were the following:

-- About one-third of PVC was produced and consumed in the United Sates, with exports less than 5 percent of total production and imports almost negligible.

-- A steadily increasing world-wide demand for PVC was attracting new production facilities in many countries, with the required technology well known on a broad international scale.

-- Import duties on PVC were 1 1/4 cents per pound plus 6 percent ad valorem from MFN countries and 4 cents per pound plus 30 percent ad valorem from others. Given the US market price of 18 to 24 cents per pound, there had been little incentive to import PVC resin.

-- Because of short supplies of PVC in the United States and unattractive foreign prices, there had been little export incentive.

-- Deaths attributable to exposure to vinyl chloride had been reported in at least five countries with regulatory action in each of these countries likely.

Against this very general type of analysis, it seemed reasonable to conclude that pollution control costs that would add several percent at most to the cost of PVC would have a very minor impact on the export/import situation. Concurrently, analyses suggested that substitute products would not significantly invade the PVC market as the result of such costs. At the same time, virtually no attention was given to what might be called the micro effects, such as the likely steps the several foreign subsidiaries planning to invest in PVC plants in the United States would take in the face of increased investment costs and the likely steps by US firms planning investments overseas.

Another recent example, with a different set of international considerations, is the current effort to phase out the manufacture and import of polychlorinated biphenyls (PCBs). Let me be specific.

- -- In 1972, a Decision of the Organization for Economic Cooperation and Development (OECD) called on member countries to limit the use of PCBs to closed electrical systems as a key step in reducing the possibilities of environmental discharge. To date, only one country, Japan, has taken the necessary steps to comply.
- -- Although PCBs manufactured in the United States are used only in closed electrical systems, imports from Europe of about 500,000 pounds annually are being used largely in open systems. There is no practical way of inventorying the imports of PCB-containing equipment.
- -- Substitutes for PCBs, and particularly silicone oils, are being introduced in Japan while other substitutes with more questionable environmental acceptability are being offered for sale by both US and foreign chemical manufacturers.

Legislation is pending which would ban all manufacture and importation of PCB -- a step which will require major adjustments in the electrical industry. Should this approach be adopted by all or at least most nations manufacturing PCBs, there is an excellent opportunity to reverse the contamination levels from this highly persistent chemical. Our principal concerns are that the replacement fluids not significantly increase energy consumption (with the well known international implications), and that regulatory actions be sufficiently stringent and well enforced to insure that the environmental gains outweigh the costs involved.

The Challenge for Public Administration

None of us are sufficiently broad in our outlook, our knowledge, or our experience to appreciate fully the dimensions of regulatory impacts at home and abroad. Thus, an institutional approach that will enrich without stifling decision-making seems in order. But what does this mean in practice?

In my view, we do not need to reorganize the Federal agencies nor create new standing committees or other organizational mechanisms to integrate international concerns into the regulatory process. Rather we should use the existing processes, and particularly the comment and hearing procedures which accompany almost every major regulatory decision, more effectively. There are offices in several Federal Departments concerned with the flow of technology across borders which do not participate in or even have an up-to-date awareness of the regulatory processes affecting the technology. Even within the regulatory agencies themselves there are organizational entities dedicated to international activities which are sensitive to global considerations but which are not fully integrated into the decision-making chain.

Industrial groups, and particularly several of the trade associations, do not hesitate to submit for the formal record and to articulate informally their international as well as domestic concerns on specific regulatory actions. This type of input is very valuable. At the same time, however, groups representing other segments of the interested public with differing perspectives are not as well equipped nor as well informed to make meaningful contributions to the record. Thus, the inputs of Federal agencies are particularly important to establish as sound a basis as possible for the eventual decisions.

With regard to the analytical tools for assessing in advance international impacts, the complexities of the chemical industry seem to defy rational analysis. Given the diversity of chemicals and their uses, the interdependences among sectors of the industry, and the seemingly constant changes in availability of substitutes, macro economic models have serious limitations. A product-by-product examination that does not lend itself to easy programming is probably the rule rather than the exception. One very useful approach in this regard is case studies of past impacts resulting from specific regulatory actions. These retrospective analyses can be helpful in developing very crude check lists for considering future actions.

Perhaps the most vexing problem is the inconsistency in regulatory approaches among the highly industrialized countries, whether the area be drug testing or the banning of specific chemicals. In my view, we have not fully utilized bilateral opportunities to achieve parallel actions by the most important Governments, and too often our multilateral efforts impress only a handful of international civil servants and consulting professors. Improved approaches seem imperative to insure that US actions taken on a unilateral basis achieve their objectives without unnecessarily jeopardizing our international competitive position.

Clearly, any Governmental decision is only as good as the capabilities of the people involved in the process leading to the decision. I doubt that any of our training grounds for Governmnental officials -- our universities, our Civil Service schools, or our Agency development programs -- have given serious consideration to the necessity for bringing together regulatory and international skills in a structured manner despite the publicity attendant to the Stockholm Conference several years ago. As our training institutions move more heavily into the interfaces of the technology and policy aspects of the regulatory sciences, the realities of modern international economics must envelop the more traditional disciplines. Perhaps this is an area where public administration can have a major impact in bringing the international dimensions into our technological decisions of the future.

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PESTICIDES AND THE TOXIC SUBSTANCES CONTROL ACT

Delivered by
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to the
State Federal FIFRA Implementation Advisory Committee
Washington, DC -- March 10, 1976

Federal regulation of certain toxic substances dates back to the beginning of the century. Pesticides have been Federally regulated for over sixty years, beginning with the Insecticide Act of 1910, while food and drugs have been regulated since 1906. Those chemicals which fall under current laws -- pesticides, drugs, and food additives -- represent, however, only 4 percent or less of existing chemicals, as measured in terms of annual sales value. While there are some 1,800 registered active pesticidal ingredients, there are over two million known chemicals of which at least 30,000 are currently in commercial production. To these are added some 1,000 new chemicals introduced in commerce each year. Of the more than two million known chemicals, only a few hundred have been adequately tested.

As stated in the introductory section of the pending Toxic Substances Control Act, Congress finds that humans and the environment are being exposed to a large number of chemical substances and mixtures each year, some of which may present an unreasonable risk to health or the environment. Accordingly, it is the stated intent of Congress to provide in the Toxic Substances Control Act adequate authority to regulate these potentially hazardous chemical substances and mixtures.

One of the main thrusts of the legislation is to provide some mechanism for ensuring that hazardous chemicals are identified and properly tested before they are exposed to humans and the environment in significant quantities. All versions of the legislation would provide EPA with authority to control certain problems before they are introduced into commerce. This important feature has often been termed a "front-end" approach. Manufacturers of new chemicals would be required to submit information concerning the quantities to be produced, uses, by-products, and any test data developed, to the Administrator prior to commercial production. EPA would have 90 days in which to review this information and initiate action, if warranted, to restrict the production or use of that new chemical. Under certain versions of the legislation, EPA might require further testing to clarify the health and environmental effects of the substances.

Some have made an analogy between this permarket notification provision and the pesticide registration process. However, such an analogy is misleading. First, Congress has not resolved the issue

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of whether all new chemicals or only ones which belong to certain chemical classes listed in advance by EPA will have to be subject to premarket notification requirements. Moreover, no version of the legislation incorporates a "registration" or "certification" requirement. In most versions of the legislation, unless EPA promulgates a rule based on a finding of unreasonable risk or a belief that there may be unreasonable risk presented by a chemical, the chemical may be marketed at the end of the 90-day period without an affirmative action by EPA. In other words, there are no extensive testing requirements mandated by the legislation to "prove" the safety or efficacy of new industrial chemicals.

Aside from the authority to review certain chemicals (and in some versions of the legislation all chemicals) prior to their introduction into commerce, the Toxic Substances Control Act could greatly enhance our knowledge about the 2 million existing chemicals. Under the reporting authority of the legislation, EPA can request information on the health and ecological effects, the distribution, the uses, the kinds and levels of exposure, and byproducts of all chemicals. Further, if the effects of a chemical are uncertain or unknown and there is reason to believe that the chemical may cause or contribute to an unreasonable risk, then EPA may require that the manufacturer of that chemical test for certain effects according to EPA standards for test protocols. EPA has broad discretionary authority over testing requirements. For example, the kinds of tests which EPA may require range from acute toxicity studies to environmental fate, carcinogenicity, and teratogenicity tests.

The information generated by the reporting and testing requirements could be very useful in the implementation not only of TSCA but of other authorities as well. For example, the Occupational Safety and Health Administration (OSHA) does not currently have authority to require manufacturers to test the effects of occupational exposure to chemicals. EPA could require such testing and the data could be used by OSHA in setting workplace standards. Insofar as a chemical is used for uses other than solely as a pesticide, EPA could require testing on such chemicals, the results of which might be of interest to EPA's Office of Pesticide Programs.

While the information generating aspect of the legislation is in some respects perhaps the most important, the pending legislation provides an important alternative to the current narrowly focused authorities directed to toxic substances. While many claim that the existing authorities are sufficient to deal with any chemical problem, the effects of these authorities are limited to three areas. First are the consumer protection statutes which have as their primary mission the prevention of acute risks to human health. A second major category of current regulatory authorities are the media-oriented statutes whose focus is typically on environmental contaminants after they are manifested at the end of an outfall pipe or smokestack. Finally, there are statutes which deal with a particular phase of the existence or use of a toxic substance, such as in the workplace or during transport, or in products such as pesticides or drugs. With the alternative being a collection of special purpose bills introduced to remedy each new crisis that can not be adequately addressed by existing laws, the pending legislation provides a clearly needed rational approach to deal with problems which fall outside the narrow scope of the existing regulatory framework.

The legislation provides authority which is not contained in any existing authorities, and which is critical to effective control of certain chemical hazards. The authority includes prohibiting or limiting the manufacture of a chemical substance or mixture. While EPA estimates that banning of a chemical altogether will be rare, perhaps once every three or more years, such an action may be the only way to cope with certain problems. Polychlorinated biphenyls (PCBs) are examples of chemicals which are so persistent in the environment and toxic to humans and wildlife, that when acceptable alternatives are developed, banning the manufacture and importation of PCBs seems to be the only effective way of controlling continued contamination and threat from these chemicals. In addition, the pending legislation provides authority to prescribe certain quality control procedures to eliminate hazardous contaminants, as well as to issue disposal and labelling requirements.

Pesticides are explicitly exempt, insofar as they are manufactured or distributed in commerce for use as a pesticide, from any regulatory action, including reporting and testing requirements. If a chemical which has both pesticidal and non-pesticidal uses could be regulated under either FIFRA or TSCA, under most versions of the legislation, the Administrator would have discretion to use what he determines is the most appropriate authority to protect against the risk. The legislation clearly states, however, that decisions to use TSCA to address a chemical problem will not affect the extent to which human health or the environment is to be protected under such other Federal law.

In contrast to other major environmental authorities, implementation of the Toxic Substances Control Act will be a highly centralized Federal activity. However, there is provision for State regulation of toxic substances similar to that in Section 24 of FIFRA. In general, States may establish or continue such regulations if they are consistent with or more stringent than Federal regulations and do not create difficulties in marketing, distribution, or otherwise unduly burden interstate commerce. Unlike FIFRA, present versions of TSCA do not authorize the Administrator to delegate to any State the authority to cooperate in the enforcement of the Act nor are there provisions similar to those under FIFRA for training.

Obviously, this legislation will be a very complicated one to implement and to coordinate, not only with the States and regions, but with other Federal agencies. There are a number of provisions in the current versions of the legislation which require the Administrator of EPA to consult with other agencies before taking certain regulatory actions. Further, the following excerpt from a recent speech delivered by Administrator Russell Train to the National Press Club underlines the intention of EPA to implement the legislation in full consultation not only with other agencies but with representatives of all major interests.

"We have done a great deal over the past several years to improve the regulatory process at EPA -- in particular, to make it far more open and equitable. Our decisions are subjected to more searching scrutiny, more critical review, from sources inside and outside the Agency and the government, than those of any other agency. We have made a strenuous and increasingly successful effort . . . to get all the major interested and affected parties actively and effectively involved throughout the process of developing a regulation. We also have the most open and rigorous process of economic impact analysis performed by any agency of the Federal government.

It is along these lines, according to these processes, that we would exercise our authority under toxic substances legislation. If the legislation does not require it, I would -- on my own -- appoint an Advisory Committee which is broadlly representative of all major interests to help advise us on implementation of the Act."

I predict that when the legislation is enacted, EPA will fully appreciate and welcome advice from those, such as yourselves, experienced in regulating toxic substances.

FLAME RETARDANT CHEMICALS AND THE TOXIC SUBSTANCES CONTROL ACT

Delivered by
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to the
National Academy of Sciences Committee on the Fire
Safety Aspects of Polymeric Materials
Washington, DC -- January 27, 1976

I would like to thank Dr. Shane and Dr. Reinhardt for inviting me to serve on this panel. I would like to begin by talking about the Toxic Substances Control Act, and then discuss one experimental technique which we hope will assist us greatly in implementing the Act. I will then mention some results which have been obtained on one flame retardant chemical, tris(2,3-dibromopropyl) phosphate.

THE TOXIC SUBSTANCES CONTROL ACT

The Office of Toxic Substances is the Office within the Environmental Protection Agency responsible for coordinating efforts to implement the provisions of the pending legislation which will hopefully soon be known as the Toxic Substances Control Act of 1976. This Act will give EPA the responsibility for determining which of the thousands of chemicals in commerce, excluding drugs, pesticides, foods and food additives, are likely to pose unreasonable risks to health or the environment. As I will mention later, flame retardant chemicals appear as a class to be among the types of chemicals which warrant attention by EPA. I would like to outline the major provisions of the pending Toxic Substances Control Act. I will base my discussion on the current version of bill H.R. 10318 (Committee Print, Jan. 9, 1976) which was recently reported out of the House Subcommittee, though most of the provisions I will mention are similar in other versions of the bill.

Basically, the Act will give EPA both the authority to obtain information necessary to assess the health or environmental impact of the manufacture or use of a chemical and the authority to take regulatory action when this is needed to reduce some health or environmental threat, taking into account the economic and social benefits derived from the chemical. This regulatory action would be taken only if the problem cannot be adequately addressed under other authorities. If EPA finds manufacture, processing, distribution in commerce, use or disposal of a chemical is likely to cause or contribute to an unreasonable risk to health or the environment -- a risk that outweighs the benefits -- then the Agency will be empowered to take necessary action along a number of lines. These include banning or limiting quantities of chemicals or labelling to require certain use or disposal procedures. The regulatory authority granted by the Act is quite broad, though it is to be applied selectively in a manner designed to prevent overlapping jurisdiction with other agencies, such as the Consumer Products Safety Commission and the Department of Labor.

The law also gives EPA broad authorities to obtain information necessary in making the judgment whether chemicals pose a risk to health or environment. These can be divided into (1) the authority to require reporting of information relating to chemicals, and (2) the authority to require testing of chemicals when there is reason to think that there may be an unreasonable risk and adequate test data are not available.

One major problem we face is to try to determine what chemicals are made and used in the United States, what are they used for, and in what quantities. The Toxic Substances Control Act would enable EPA to require, when necessary, manufacturers and processors of chemicals to report what chemicals they are making, the uses of these chemicals, the amount produced for each use, the by-products of manufacturing, processing, use, and disposal of the chemical, all existing data concerning adverse environmental and health effects, and an estimate of the number of people occupationally exposed to the chemical. This information, if we learn to code, store, manipulate, and retrieve it effectively, will obviously help us enormously in setting priorities for further risk assessment.

According the House bill, H.R. 10318, once EPA has compiled an initial list of chemicals in commerce, anyone who wants to make or use a chemical not on the list must notify EPA at least 90 days in advance of their intention to make or use a new chemical. However, the Administration considers that this premarket notification should be limited to selected classes of chemicals set forth on a premarket notification list. In any event, similar notification is required for significant uses of old chemicals. EPA will then have the opportunity to review the relevant information prior to marketing and may decide that certain tests are required.

I have mentioned both the authority to regulate chemicals and the authority to obtain data relating to the production and uses of chemicals. My principal interest is with the third type of authority granted by the law: the authority to require manufacturers and processors of chemicals to test these chemicals in order to help us determine whether they pose an unreasonable risk to health or the environment. The types of tests which can be required under the law span a wide range.

We usually categorize tests into four groups.

First, there are tests relating to the chemical composition and physical properties of the chemical product. This could include not only such paramters as melting and boiling points and molecular structure of the principal component, but also in some cases an identification and quantification of significant impurities. Secondly, there are tests which give insight into the environmental fate of chemicals, including tests for persistence, movement through various environmental compartments, bioaccumulation potential, and monitoring around points of possible release into the environment.

The third type of tests includes test for effects of chemicals on the environment, here defined as including everything but humans. Determinations of toxicity to fish and birds are examples of such tests. The fourth category of tests includes those which are designed to tell us something about the effects of a chemical on human health. This would include both toxicological and epidemiological investigations.

Depending upon the circumstances, the bill provides that either the manufacturers of a chemical, the processors, or both would be responsible for ensuring that any required tests are performed. There is a cost sharing provision in the bill to enable all interested parties to divide the responsibility for obtaining the data, thus avoiding needless duplication of effort. In addition, there is a provision for partial reimbursement of costs by parties who decide to enter a market after others have had required testing performed. Equitable administration of this cost reimbursement provision may become quite a problem for EPA.

Reports in the last week concerning the results of the FDA investigation of the testing facilities of a major drug house, Searle & Co., have brought to light another potentially difficult problem relevant to the Toxic Substances Control Act, namely, the maintenance of the accuracy and completeness of test data submitted by industry and of the public's confidence in the integrity of such data. Obviously procedures will have to be worked out to deal with this potential problem.

Another difficult problem we have to face in implementing the testing provisions of the Toxic Substances Control Act is the selection of those chemicals or chemical classes which should be subjected to test requirements and the designing of the standards for the test to be performed. The Stanford Research Institute has compiled a list of approximately 27,000 commercially available chemicals other than those used only as laboratory reagents. Even this list is certainly incomplete. Obviously we cannot rely on full scale environmental and toxicological evaluations of all these chemicals to decide which ones require further testing. We need some way of establishing priorities.

Ideally, we would like simple, rapid, inexpensive, and reproducible test methods which can be applied to hundreds or thousands of chemicals and which are predictive of effects of interest to us. Such tests should have a near zero rate of so-called false negatives, that is, results which falsely indicate the safety of a chemical which is really a hazard. In addition, the rate of false positives should be reasonably low.

One area in which such a "prescreen" test seems to hold great promise for the purpose of prioritizing chemicals for more elaborate testing is in the correlation between mutagenicity of chemicals to bacteria and carcinogenicity to mammals. I would like to discuss the Ames test for mutagenicity in bacteria, both how it is performed and what it may mean.

THE AMES TEST:

Attempts in the 1950's to determine whether there was a correlation between carcinogenicity and mutagenicity of chemicals led to the conclusion that no such correlation exists. Even at that time, however, it was recognized that the lack of correlation could have been due, at least in part, to differences in the metabolic fates of the chemicals in the different organisms used to assay carcinogenicity and mutagenicity. As our understanding of the action of carcinogens increased, it became evident that many chemicals cause cancer when administered to experimental animals only after they have been altered biochemically to other chemicals. Aromatic amines, for example, appear to require N-hydroxylation before they can exert their carcinogenic action; polycyclic hydrocarbons appear to require epoxidation. Recognizing the significance of these findings for the correlation between bacterial mutagenicity and carcinogenicity, several investigators including Dr. Bruce Ames set out to determine if carcinogens would induce mutations in bacteria in the presence of enzymes capable of converting the parent compound to active metabolites which might be formed in mammals. Since the liver appears to have the broadest spectrum of metabolizing capability of any mammalian organ, Dr. Ames used extracts of rat liver to "activate" his test compounds.

The Ames test is performed as follows . . . [Discussion of the methodology to be given here. For a complete description of the protocol, see Ames, B. N. et al., Mutation Research, 31, 347-364, 1975].

Ames' group has compiled information on the bacterial mutagenicity and carcinogenicity of about 300 chemicals and found that, using his bacterial strains and the rat liver activating system, about 90% (157/175) of the carcinogens show up as mutagens, and about 13% (14/108) of the chemicals classified as non-carcinogens showed up as mutagens. In a paper soon to appear in the Proceedings of the National Academy of Sciences, McCann and Ames discuss possible explanations for the false negatives and false positives in the test. I will give Dr. Shane a copy of this paper to distribute to interested committee members.

It is possible that unknown chemicals found not to be mutagenic in the Ames test may be carcinogens nonetheless. Hopefully further refinements in the bacterial strains and in the techniques will reduce the number of these false negatives. There also may be some noncarcinogens which will give a mutagenic response in the Ames test. Regulatory agencies and most others concerned with safety evaluation are not at this point prepared to decide that a chemical is a carcinogen based upon a positive result in a bacterial mutagenesis test. At the same time, however, we cannot ignore the weight of the evidence which has been compiled showing a strong correlation between carcinogenicity and mutagenicity. A positive result in the Ames test would seem to cast a high level of suspicion on a chemical. Thus, while the significance of a negative result in the Ames test may be questioned, it may be reasonable to conclude that a chemical which is positive and to which humans are exposed should be subjected to a more thorough toxicological investigation, including an evaluation of carcinogenic potential. While EPA has not reached any final conclusions in this regard, this type of approach appears to have many attractive features.

FLAME RETARDANT CHEMICALS:

In considering chemicals which are appropriate for evaluation under the provisions of the Toxic Substances Control Act, chemicals such as flame retardants, especially those used for textiles, would seem to be among the candidates. First, they are relatively new products. They have achieved a very high level of widespread human exposure in a short period of time and this exposure is expected to increase in the future. Some of them are brominated, and alkyl bromides may be expected as a class to include a number of good alkylating agents. There is evidence that alkylating ability may be correlated with mutagenicity and carcinogenicity. Some of them are phosphate esters, which may raise questions about both cholinesterase inhibition and delayed neurotoxicity.

Many people first had their attention drawn to the possible problems associated with flame retardants by an advertisement which appeared in 1974. This ad pictured a little girl holding a doll and wearing pajamas which were flame retardant due to the presence of vinyl bromide. While I don't know if there is any available vinyl bromide monomer in such pajamas, the structural similarity of this compound to vinyl chloride and the use to which it was being put impressed many people. Vinyl bromide has, like vinyl chloride, been reported to be mutagenic in the Ames test.

Since the Ames test and certain other mutagenicity tests using microbes appear to have such great promise as indicators of carcinogenicity, we have let a contract to Dr. Herbert Rosenkranz of the Columbia University College of Physicians and Surgeons to test about 80 chemicals representing a wide range of industrially significant products. He has found that one of the compounds, tris(2, 3-dibromopropyl) phosphate, was mutagenic to one of the Ames strains of Salmonella, TA-1535. Dr. Ames has told me that his laboratory has also found tris to be mutagenic, thus confirming

Dr. Rosenkranz' result.

It is still possible that the mutagenicity of commercial samples of tris could be due to an impurity. Since the results from 9 different commercial samples were roughly similar quantitatively, if they were due to an impurity it must have been an impurity that was relatively constant in all samples, including HV (high volatiles) and LV (low volatiles) samples.

Dr. David Brown of the Stauffer Chemical Company obtained a sample of highly purified tris for Dr. Rosenkranz. The mutagenicity of this material was compared to that of the commercial grade. The results showed that the purified chemical has roughly the same mutagenic potency as the commercial tris(2, 3-dibromopropyl) phosphate.

A published paper by Dr. Fred Kerst of the Michigan Chemical Company lists several known impurities in commercial tris. Dr. Rosenkranz obtained samples of these and tested them for mutagenicity. The impurities are 2, 3-dibromopropanol, 1, 2, 3-tribromopropane, and 1, 2-dibromo-3-chloropropane. While each of these chemicals did show mutagenic activity, the activity was not sufficient to account for the mutagenicity of the commercial tris(2, 3-dibromopropyl) phosphate.

It would thus appear likely that the mutagenicity of commercial tris can be attributed to the compound tris(2, 3-dibromopropyl) phosphate itself rather than to an impurity.

As I stated before, a positive result in the Ames test does not, in itself, constitute a sufficient basis for concluding that a chemical is a carcinogen. It does, however, raise suspicions. The work of Dr. Lisk's group at Cornell and the work on contact sensitization at DuPont raise the possibility that significant exposure to, and perhaps absorption of, tris can occur from normal use of this chemical in children's sleepwear. The work of these groups also indicates that release of this chemical to the environment may occur during laundering of treated fabric. When these experiments are considered in light of the mutagenicity results, it would appear that certain steps should be promptly taken concerning this chemical.

Given the industrial investment in tris, there would probably be a reluctance to abandon this chemical on the basis of the available test results. However, it would be appropriate to conduct further experiments to determine whether or not there is in fact any hazard. The mutagenicity data point out the need for further work on the bioavailability of tris from fabrics, the carcinogenicity of tris and, possibly, its mutagenicity in other test systems. The basic premise behind the Toxic Substances Control Act is that industry should finance the testing of chemicals it makes and uses. We hope the manufacturers and users of tris will support the necessary research on this chemical.

The lesson I have learned so far from my reading about flame retardant chemicals is that the following of standard safety testing procedures by industry or by government, while better than no testing at all, is no substitute for the work of interested and innovative researchers, such as those at Cornell, at DuPont, and at the University of Utah. Flame retardant safety is obviously an area requiring more than the rote performance of routine tests. Routine testing of tris, for example, failed to indicate any potential problems. Only if those involved show a willingness and ability to seek out and analyze potential problems in innovative ways will we be able to find and deal with any problems which may exist in a responsible and timely fashion and thus reduce the possibility of flame retardants from becoming next month's toxic substance of the month.

ADDRESS TO THE CONFERENCE ON THE ENVIRONMENTAL IMPACT OF WATER CHLORINATION

Delivered by
Edward M. Brooks
Chief, Special Projects Branch

to the
Conference on the Environmental Impact on Water Chlorination
Oak Ridge National Laboratory, Oak Ridge, Tennessee
October 22, 1975

I'm delighted to have the opportunity to talk to you this evening. I must confess that, being neither scientist nor engineer, I approach the opportunity with no little trepidation. I am somewhat consoled by the fact that my topic has to do with decision-making in the regulation of chemicals, since most decision-makers in this area are also not scientists -- a fact which must no doubt frustrate many of you from time to time. Of course there is that body of opinion which holds that the regulation of toxic substances is too important to leave to toxicologists. In any event, the information exchanged -- or lack thereof -- between scientists and the decision-maker is what I want to discuss tonight.

When he approached me to give this talk, Dr. Jolley was kind enough to suggest a number of questions I might address, among which I found four particularly provocative:

1. What type of toxicity data are considered in making regulations?
2. Can cost-benefit analyses be applied in developing regulations?
3. What is the mechanistic procedure or protocol for developing regulations? and
4. What can data generators do to make decision making easier?

All four questions touch upon a more general proposition I now put to you, namely that regulations to control serious chronic toxicants are not developed within a consistent logical framework. I will first demonstrate the truth of this general proposition, and then explore a few reasons why it is the case and what, if anything, ought be done. Before embarking let me define, for purposes of discussion, two key phrases in Brooks' proposition. By "serious chronic toxicants" I mean those that are of concern because they may cause death or illness to humans -- either after many years of continuous exposure, or after a latency period of many years, -- at levels markedly below the dosage at which the tolerable levels of risk can be detected in laboratory test animal experiments. Such toxicants include, but are not, in my opinion, limited to, human chemical carcinogens.

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The term "consistent logical framework", refers to a system that imposes a stipulated set of values, principles and rules upon the manner in which data are evaluated and exploited to reach decisions -- such that different players, operating independently with the same information, or lack of information, reach essentially the same conclusions. A major function of such a system is to compel consideration of costs, risks and benefits across the range of available regulatory options.

The value of such a rational approach to regulatory decision-making is generally appreciated. The National Academy of Sciences recently completed a study entitled Decision Making for Regulating Chemicals in the Environment,(1) the fruit of which is a series of 34 recommendations -- from four of which I quote in part.

> "17. The quality of chemical regulatory decisions is dependent largely upon the adequacy of the available information. To develop an adequate data base, research efforts in basic clinical and environmental toxicology and epidemiology and in economic analysis must be strengthened . . ."
>
> "30. Highly formalized methods of benefit-cost analysis can seldom be used for making decisions about regulating chemicals in the environment. However, benefit-cost and decision frameworks can be useful in organizing and summarizing relevant data on regulatory alternatives which the decision maker must review."
>
> "31. Value judgments about noncommensurate factors in a decision such as life, health, aesthetics, and equity should be explicitly dealt with by the politically responsible decision makers and not hidden in purportedly objective data and analysis."
>
> "32. The decision process should require the agency's technical staff to present a full set of options with a corresponding range of cost-benefit-hazard data and explicit statements on the confidence limits of each analysis."

The Academy thus expects staff scientists to identify several regulatory alternatives and objectively estimate and present to the politically accountable decision-maker the costs, risks and benefits associated with each -- together with explicit probability statements regarding the reliability of those estimates. From these analyses the decision-maker selects a regulatory option and, in proposing and promulgating the decision, explicitly sets forth the value judgments he applied.

'Tis a consummation devoutly to be wished.

It will be instructive to look at a few proposed or promulgated regulations to see how closely they approach this ideal. I emphasize two points. First, nothing that follows is intended as criticism of any given regulatory agency or decision. Further, where discrepancies are found between different regulations controlling the same substance I offer, in these remarks, no opinion regarding their relative merits. My purpose here is to examine what has been done to assess possible weaknesses in the process rather than in any particular regulation. Secondly, I trust it goes without saying that any weaknesses found hardly constitute grounds for not continuing to aggressively implement our diverse authorities as best we can. I will now discuss four proposed or promulgated standards -- two for asbestos and one for vinyl chloride and aflatoxins.

Clean Air Act -- Sec. 112 -- Asbestos:

In April of 1973, EPA promulgated a regulation (2) to control asbestos emissions at a level designed to protect human health with an "ample margin of safety". In the preamble to this standard the Agency stated that no numerical concentration or mass emission limit was practicable because it is "impossible to estimate even roughly the quantitative relationship between asbestos-caused illness and the doses that cause those illnesses". Although we concluded that there are no levels known at which asbestos does not involve risk, and that the effects of inhaling asbestos are cumulative, we did not ban the substance outright because to do so would prohibit many extremely important activities. Accordingly the standard, in major part, simply banned "visible emissions" of asbestos.

OSHA -- Sec. 6 -- Asbestos:

One week ago Thursday last, the Occupational Safety and Health Administration of the Department of Labor proposed a new standard (3) to regulate work place exposure to asbestos. The initial OSHA asbestos standard, (4) promulgated in May of 1971, was 12 fibers, not longer than 12 micrometers, per cubic centimeter. In December of 1971 (5) this was reduced to five fibers, no longer than five micrometers. The current standard, (6) promulgated in 1972, established the level at five fibers, but added the provision that this would automatically go down to two fibers on July 1, 1976. Now the October 9 proposal would reduce the level, still further, to 0.5 fibers. The proffered rationale is that (1) sufficient evidence has accumulated to warrant designating asbestos a human carcinogen, (2) a "no effect" level has not been demonstrated, and (3) in the absence of evidence to establish a safe level, employee exposure must be reduced "as low as feasible".

Thus both EPA in its promulgation under Sec. 112 of the Clean Air Act and OSHA in its promulgation under the Occupational Safety and Health Act concluded that there is no known exposure level for asbestos at which adverse human health effects do not occur. Within that framework EPA concluded that no numerical concentration limit is possible because the dose-response relationship is unknown, while OSHA not only established a numerical limitation, but has systematically reduced it over the years.

The significant point is that no data have been provided to the decision-maker in either Agency regarding the dose-response relationship. Relative hazard assessment is therefore out of the question. In this regard it is worth noting that, although the rationale for the OSHA standard is to reduce exposure levels to as "low as feasible", no evidence is provided to suggest that 0.5 fibers is either feasible or safe. In point of fact the rationale and evidence used to justify the 1972 five fiber standard could just as well have been used to justify the 1975 0.5 fiber proposal, and vice versa. The evidence to establish a "no effect" or "safe" level was just as absent when OSHA promulgated the five fiber standard to protect against asbestosis as it was a week ago Thursday last when it proposed the 0.5 fiber standard to protect against mesothelioma -- and this lack of evidence has nothing apparent to do with any special attributes of carcinogens. In neither instance were "no effect" levels or dose-response relationships established.

I now want to contrast the OSHA vinyl chloride standard with the tolerance for aflatoxins proposed by the Food and Drug Administration.

OSHA -- Sec. 6 -- Vinyl Chloride:

In October of 1974 OSHA promulgated a standard(7) for vinyl chloride based on (1) the fact that 31 vinyl chloride workers had died of angiosarcoma of the liver, (2) Maltoni's experiments inducing angiosarcoma in rats at 250 parts per million, and (3) Industrial Bio-Test Laboratories' studies inducing angiosarcoma in rats and mice at 50 ppm. OSHA concluded, in accordance with the 1970 Report of the Surgeon-General's Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens, that, on the basis of the demonstration of cancer in two animal species, vinyl chloride posed a carcinogenic hazard to man. In further accordance with that Report, OSHA took the position that "safe exposure levels for carcinogenic substances can not be scientifically determined" -- a position supported at the Hearings by both NIOSH and NCI. On the grounds that vinyl chloride is a carcinogen and "safe" levels for carcinogens cannot be established, OSHA promulgated a "no detectable level" standard as measured by methods sensitive to one ppm.

FD&CA -- Sec. 406 -- Aflatoxins:

The Food and Drug Administration's proposed December, 1974, tolerance for aflatoxins(8) in shelled peanuts and peanut products, provides an interesting contrast. The Federal Register NPRM notes that 25 rats, fed aflatoxins at 15 parts per billion, all developed liver cancer, as did monkeys fed aflatoxins. In addition, epidemiological studies in Southeast Asia and Africa indicated a correlation between the incidence of liver cancer in humans and exposure to aflatoxins. FDA concluded from this that aflatoxins were "poisonous or deleterious substances" and that human exposure should be held to the "lowest level possible".

An FDA survey indicated that four percent of the U. S. peanut butter exceeded the 20 ppb level, seven percent exceeded 15 ppb, 11 percent exceeded 10 ppb, and 25 percent approximated one ppb. Thus, about four percent of the U. S. production fell between 10 and 15 ppb, and three percent between 15 and 20 ppb. FDA proposed a 15, rather than 10, ppb tolerance to "avoid causing significantly increased losses of food".

Thus, in quite comparable situations -- with substances demstrated to be carcinogenic in two animal species and with strong epidemiological evidence implicating them as human carcinogens -- OSHA promulgated a "no detectable level" standard (for vinyl chloride) well below the lowest levels at which any adverse effects have been found in any species, while FDA proposed a tolerance (for aflatoxins) at the same level at which 25 of 25 mice developed liver cancer. The two Federal Register Notices reflect the different philosophies. First the OSHA text regarding vinyl chloride.

> "There is little dispute that vinyl chloride is carcinogenic to man and we so conclude. However, the precise level of exposure which poses a hazard and the question of whether a 'safe' exposure level exists cannot be definitively answered on the record. Nor is it clear to what extent exposures can be feasibly reduced. We cannot wait until indisputable answers to these questions are available, because lives of employees are at stake. Therefore, we have had to exercise our best judgment on the basis of the best available evidence. These judgments have required a balancing process in which the overriding consideration has been the protection of employees, even those who may have regular exposures to vinyl chloride throughout their working lives".

And the counterpart passage from the FDA proposal regarding aflatoxins.

> "In addition, because there is no direct evidence that aflatoxins cause cancer in man or of what may be the level

of no effect, the Commissioner cannot conclude that there is any tangible gain from lowering the permissible level to either ten or five ppb. Such uncertain benefit to the public health must be weighted against the clear loss of food that would result."

Again the point is not who, if anyone, is right or wrong, but rather that no data were provided to either decision-maker to permit a reasoned analysis of the risks incurred at various possible exposure levels. Without such information the levels can and will be set almost anywhere from zero up to the levels that obtain without any regulation at all. Any consonance between such permitted exposure levels, and a balanced tradeoff between health and economic impact considerations, will be purely fortuitous.

The inadequacies of these regulations warrant a moment's reflection. Most remarkable is the fact that none makes any attempt to specify an "acceptable" level of risk. Instead they offer analytically meaningless platitudes about the need to reduce exposures "as much as possible" or "feasible". There are no estimates of the extent of the adverse human health effects presumed to be caused by these substances, much less of the extent to which this incidence is expected to be reduced by the regulation. Not only is it impossible to evaluate how well these regulations achieve their objectives -- we can't even define the objective. In the most fundamental sense, then, it is impossible to assess their worth.

Even if "acceptable" levels of risk had been established, however, there are still no health effects data available to indicate the exposure levels at which those risk levels would be exceeded. In this situation it is fatuous to speak of cost-risk-benefit analyses, judicious tradeoffs, balancing competing factors, or any other phrase that connotes a reasoned application of useful information.

One must ask how this came to pass? How is it we write regulations in such an important area with so little comprehension of what we are about? From whence comes the pressure to promulgate such regulations? Why is the scientific documentation such a paltry product? What impels decision-makers to act upon such tenuous evidence? Aside from our ignorance, what accounts for the striking inconsistencies found in these regulations -- not only in their stringency but, more basically, in their underlying philosophy?

While there are obviously many reasons, I would like to briefly mention two contributing factors. First I believe that we may sometimes be moved to precipitate and unwarranted action in response to public pressure. In this regard, incidentally, I have just read a perceptive article in the Fall issue of The Public Interest(9) which reflects my concern precisely. I commend it to your attention and will attempt to whet your appetite with the following quote.

> "Of all the heresies afloat in modern democracy, none is greater, more steeped in intellectual confusion, and potentially more destructive of proper governmental function than that which declares the legitimacy of government to be directly proportional to its roots in public opinion -- or, more accurately, in what the daily polls and surveys assure us is public opinion. It is this heresy that accounts for the constantly augmenting propaganda that issues forth from all government agencies today -- the inevitable effort to shape the very opinion that is being so assiduously courted -- and for the frequent craven abdication of the responsibilities of office in the face of some real or imagined expression of opinion by the electorate."

This tendency to precipitate action in the face of uninformed but aroused popular opinion is reinforced by the wide and increasing discrepancy between our ability and disposition to detect the presence of potential toxic substances and our ability to assess the degree of risk they pose. EPA's recent and continuing concern with organics in drinking water illustrates this phenomenon. Surveillance and analytical technology now yields impressively precise quantification of very low levels of organics in water, while the state of the health effects assessment art apparently permits only crude qualitative estimates of the human health hazards posed at these levels. In 1969 the Federal Water Pollution Control Administration found chloroform, benzidine and bis-chloromethyl ether in the New Orleans drinking water.(10) In 1974 EPA found 66 organic chemicals in the New Orleans drinking water.(11) This past year we completed a survey of the water in 80 cities and found at least one of the six organics for which we sampled -- and most particularly chloroform - in every location.(12) At various stages in the course of these events substantial pressure was brought to bear on EPA to "do something". But what do we really know? When asked to review the findings of the 80 city National Organics Reconnaissance Survey, EPA's Science Advisory Board concluded that

> "... there may be some cancer risk associated with consumption of chloroform in drinking water. The level of risk, estimated from consideration of the worst case and for the expected cancer site for chloroform (the liver) might be extrapolated to account for up to 40% of the observed liver cancer incidence rate. A more reasonable assumption, based upon current water quality data which show much lower levels than the worst case in the majority of U.S. drinking water supplies, would place the risk of hepatic cancer much lower and possibly nil. Further, it is emphasized that both the experimental carcinogenicity data and the mathematical and biological extrapolation principles used to arrive at the upper estimate of risk are extremely tenuous. Epidemiologic studies do not, thus far, support the conclusion of an increased risk of liver cancer; although hypothesis

formulating studies in southern Louisiana suggest the possibility of an association with contaminated water and overall high cancer incidence."(13)

There is no obvious solution to this problem. It is clearly important for a public agency to be responsive to the public; this notwithstanding it is at least equally important to allocate resources and conduct the public's business in an orderly and reasoned manner.

There is also apparently no immediate solution to our inability to quantify the human health risks associated with low levels of chronic toxicants. As I understand it, neither epidemiology nor test animal experiments provide a really acceptable solution. The uncertainty regarding exposure level, the long latency or exposure periods, and the confusion created by multiple exposures, all diminish the utility of epidemiology. On the one hand, the problem of translating from test animal to human response and, perhaps more importantly, the high dose/low dose extrapolation problem, seriously limit the utility of test animal experiments. This problem is so serious that Messrs. Hoel, Gaylor, Kirschstein, Saffiotti and Schneiderman, in a recent article in the first edition of the Journal of Toxicology and Environmental Health,(14) flatly state that

> "There is no adequate method for determining the best estimate of risk for a given dose and the best estimate of dose for a given risk. Because of model dependency there does not appear to be a reliable method for obtaining such direct estimates and their required confidence limits."

I have been given to understand that the National Center for Toxicological Research was established, at least in part, precisely in order to illuminate this problem by using very large numbers of test animals to generate experimentally derived points much lower on the dose-response curve. I certainly hope my understanding is correct -- and that NCTR is soon successful in this endeavor -- for until we can quantify the human health risks associated with very low levels of serious chronic toxicants I see no hope of materially improving the standard-setting process.

FOOTNOTES

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5. Occupational Safety and Health Administration. Emergency Standard for Exposure to Asbestos Dust. Federal Register, Vol. 36, No. 234 - December 7, 1971, p. 23207.

6. Occupational Safety and Health Administration. Standard for Exposure to Asbestos Dust. Federal Register, Vol. 37, No. 110 - June 7, 1972, p. 11318.

7. Occupational Safety and Health Administration. Standard for Exposure to Vinyl Chloride. Federal Register, Vol. 39, No. 194 - October 4, 1974, p. 35890.

8. Food and Drug Administration. Aflatoxins in Shelled Peanuts and Peanut Products Used as Human Foods, Proposed Tolerance. Federal Register, Vol. 39, No. 236 - December 6, 1974, p. 42748.

9. Nisbet, Robert. "Public Opinion Versus Popular Opinion", The Public Interest, Number 41, Fall 1975, p. 166.

10. "Industrial Pollution of the Lower Mississippi River in Louisiana." U.S. Environmental Protection Agency, Region VI, Dallas, Texas, April, 1972.

11. "New Orleans Area Water Supply Study." Lower Mississippi River Facility, Slidell, Louisiana and U.S. Environmental Protection Agency, Region VI, Dallas, Texas, November, 1974.

12. "National Organics Reconnaissance Survey." U.S. Environmental Protection Agency, Office of Research and Development, Cincinnati, Ohio, April, 1975.

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PERSPECTIVES ON TOXIC SUBSTANCES CONTROL

Delivered by
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to the
Industrial Health Foundation, Inc. -- Annual Meeting
October 22, 1975

While most American television viewers were avidly watching the Red Soxs' five to four triumph in the fourth game of the World Series last week, perhaps one of the most cogent presentations documenting the "American Way of Cancer" was shown. Although those involved in industrial health are well aware of the problems of chemical substances in the workplace, the CBS special attempted to educate the American public about the pervasive presence of carcinogenic substances. Scenes of a backyard barbeque with hot dogs that might cause the formation of nitrosamines and chocolate cake that might be colored with Red Dye 2 were interspersed with scenes of Asarco's Tacoma smelter and DuPont's Chambersworks factory where exposure to potential cancer-causing substances was more obvious.

As part of the hour-long documentary, EPA Administrator Russell Train commented on the pending toxic substances control legislation. Train emphasized the need for this legislation to provide an overall approach to the problem of toxic substances. Presently, too often the Nation's population and environment provide the testing grounds for determining the effects that a chemical may have on human health or the environment. While billions of pounds of new chemicals have been introduced in the past decades, we have enjoyed their copious benefits without fully understanding their concurrent risks. Dozens of chemicals have been cited at Congressional hearings on the toxic substances control legislation as examples of substances which were once considered safe for widespread use and which were discovered to have serious adverse effects for man or his environment. The tragic consequences associated with workers' exposure to vinyl chloride and asbestos are familiar to us all. The problems presented by others, such as polychlorinated biphenyls in the nation's waterways, arsenic in the environs of smelters, and suspected carcinogens in drinking water, have also received national attention. However, the effects associated with the abundant array of remaining chemicals to which we are commonly exposed are uncertain.

The growing evidence of a correlation between exposure to industrial chemicals and cancer has prompted Dr. Umberto Saffiotti of the National Cancer Institute to comment, "Cancer in the last quarter of the 20th century can be considered a social disease whose causation and control are rooted in the technology and economy of our society." Other health problems such as birth defects, heavymetal poisoning, and respiratory and other disorders are also traceable to chemical substances intentionally or unintentionally present in air, water, and food. The adaptability of man and the environment to the myriad of chemicals introduced is clearly being challenged, with signs indicating a serious deficiency in Nature's ability to cope.

The outcome of this competition clearly rests upon the precautionary measures that are developed to limit exposure to chemicals when necessary without unduly curtailing the economic and other benefits associated with them. The pending toxic substances control act would provide a critical tool for developing a coherent approach to prioritizing toxic chemicals for attention, for assessing risks, and for balancing costs, risks, and benefits in making regulatory decisions.

During the course of the long debate over the pending legislation, spokesmen from the chemical industry have often argued that present authorities are sufficient to address the problems of toxic substances. While these authorities may appear to be numerous, their effects are limited to three broad areas. First are consumer protection statutes which have as their primary mission the prevention of acute risks to human health. For the most part they do not extend to products which are not strictly "consumer" products such as those in industrial or commercial use. Consequently, although fluorocarbons such as Freon can be banned from household aerosol spray cans, a large percent of these fluorocarbons cannot be regulated as they are used in industrial operations. Further, these statutes do not address problems of environmental protection nor human exposure to toxic substances through environmental routes.

A second major category of current regulatory authorities are the media-oriented statues whose focus is typically on environmental contaminants after they are manifested at the end of an outfall pipe or smokestack. These authorities are designed to control the "accessible" aspects of a toxic chemical problem which, unfortunately, may not always be the "critical" aspect of the problem. This approach may hamper efforts to cope with the core of the environmental and health risks posed by the manufacture, use, and disposal of toxic substances.

Finally, there are statutes which deal with a particular phase of the existence or use of a toxic substance such as in the workplace or during transport, or as used as a pesticide or drug. With the alternative being a collection of special purpose bills introduced to remedy each new crisis, the pending legislation provides a clearly needed rational approach to deal with problems which fall outside the narrow scope of the existing regulatory framework.

One critical aspect of the legislation is the authority to control certain problems before they appear in the environment. This important feature has often been termed a "front-end" approach. As you probably know, the legislation would require premarket notification of all new chemicals in commercial quantities and significant new uses of existing chemicals. Information concerning the quantities to be produced, uses, and by-products would be submitted to the Administrator prior to commercial production. If there was reason to believe that the intended production or uses of the substance posed an unreasonable risk, appropriate action could be taken to limit the production or use or to require further testing to clarify the health and environmental effects of the substance.

While no one pretends that all potential hazards associated with the chemicals submitted for premarket review could be anticipated during the 90-day review period, nonetheless those who may potentially benefit from such an approach are not only the worker, consumer, and environmentalist, but also the producer. By examining the potential dangers associated with the production and use of a product before investing considerable capital, the chemical industry can later avoid the serious disruption and losses attendant to remedial action after the fact. This approach should be far more attractive to industry than the present unpredictable and sometimes costly system of ad hoc controls.

Another major criticism raised by opponents of the legislation is the estimated costs and economic impact that it would have on the chemical industry. The reports of the Manufacturing Chemists Association and Dow Chemical Company are cited by industry as the basis for their claims that the legislation would adversely affect the chemical industry. While the industry studies project costs to industry of up to $1.3 and $2 billion annually, a study done by EPA estimates the costs will range up to a little over $100 million.

The major discrepancies between the cost estimates prepared by industry and EPA are largely based on differing assumptions concerning EPA implementation strategies and concerning adjustments by industry with regard to the overall approach to development of new products as a result of the existence of the legislation. In general, EPA's cost estimates are based on assumptions concerning the selective implementation of the Act, whereas the other studies assume across-the-board requirements for testing and extensive regulatory actions.

For example, the Dow study assumes that about $1 billion would be lost to industry each year due to regulatory actions which result in the abandoning of the equivalent of 48 industrial facilities valued at $20 million each. The clear implication is that uncontrolled industrial chemicals are currently causing widespread environmental damage--damage so extensive that after consideration of both the environmental risks and economic benefits associated with such chemicals, an annual cost of $1 billion for corrective action by industry would be warranted. Both MCA and EPA assume that major regulatory actions such as a ban on the production or major use of a substance would be infrequent, perhaps one ban every three to five years with one or two major use actions taken each year.

On the other hand, the MCA study assumes that industry would test all new chemicals and new applications as if EPA required them to be tested. This reasoning results in costs that are equivalent to mandatory testing requirements. However, such testing requirements are contrary to the intent of the legislation, which is that testing requirements should be discretionary and selectively applied.

In considering testing requirements, currently regulated chemicals such as pesticides do not provide a good analogy with chemicals subject to the proposed legislation. Pesticides are deliberately toxic and are deliberately dispersed widely into the environment. By using the analogy of pesticide testing requirements, the industry studies present a somewhat distorted picture of what is likely to happen with testing of currently unregulated chemicals, both in terms of the quantity of chemicals likely to be tested and the costs of individual test requirements.

In recognition of the differences between industrial chemicals and pesticides, food additives, and drugs which are currently subject to stringent testing requirements, the Administration and Congress have repeatedly rejected the concepts of registration and certification for industrial chemicals. Nonetheless, an analogy is frequently made between the impact of the Drug Amendments of 1962 and the potential impact of the pending toxic substances legislation in terms of product innovation. While requirements for extensive testing and certification are mandated for new drugs, similar requirements are not mandated for industrial chemicals under the pending legislation. Aside from this, the hypothesis that the industrial chemical industry may suffer economically if the present level of product innovation is not maintained seems to be contradicted by the drug industry's growth in profits during the ten years after the implementation of the Drug Amendments even though the number of new drugs declined during those years.

Finally, industry's projections of the effect of the legislation on unemployment are difficult to accept. Using an economic input-output model, the MCA study estimates unemployment rates of 20,000 to 80,000 annually. However, these projections are outside the range of sensitivity of the model that was used. In this regard, spokesmen for the AFL-CIO have indicated that the unemployment impact of 1,000 annually was a reasonable estimate.

In conclusion, any of the costs of the impact of the legislation must be measured against $105 billion spend on national health costs and approximately two million work-years lost due to cancer alone each year. Compared with these costs, a limited investment in preventive testing and other measures seems reasonable.

Perhaps the issue of most interest to you is how the pending legislation would enhance present authorities directed to industrial health concerns. As Sheldon Samuels of the AFL-CIO testified before the Senate last July, the millions of Americans in the industrial workforce "have the most to gain or to lose by the control or failure to control the proliferation of toxic substances in the environment of the workplace and the community." While the Occupational Safety and Health Act of 1970 provided important authority to remedy present conditions, it did not provide for the screening and control of chemicals prior to their entry into the workplace. As discussed earlier, the premarket review requirements of the pending legislation provide such a preventive, "front-end" approach to identifying and preventing exposure to chemical hazards.

A further shortcoming of the present authorities available to address occupational health problems is the lack of authority to require the generation of safety data. Although OSHA allows for some measure of regulatory control for known toxicants, in the case of chemicals whose effects are unknown or only partially known, the Government currently must sponsor its own testing program to determine the safety of the substance. Under the toxic substances control legislation, EPA may require that industry perform tests according to EPA standards for test protocols if there is reason to believe that the chemical presents or may present an unreasonable risk to human health or the environment. Such testing may range from acute tests to carcinogenicity or teratogenicity tests.

In determining which chemicals to test, EPA will consult and coordinate with the Department of Labor and other relevant agencies. Occupational exposure considerations will certainly be a significant factor in selecting testing candidates. However, it should be emphasized that the pending legislation is clearly intended to complement and supplement existing laws and regulations such as the occupational health safety requirements. In implementing any part of the toxic substances control legislation, EPA will be careful not to overlap with any existing authority such as OSHA.

In addition recent versions of the legislation provided EPA authority to require industry to send lists of and, if desired, health and safety studies concerning the effects of a chemical substance, including occupational exposure and clinical studies. These aspects of the legislation have the potential to enhance greatly the present information concerning chemical hazards in the workplace.

While workers in the chemical and related industries are most directly exposed to toxic substances, as documented on the CBS special the average American is coming in contact with chemicals with increasing frequency and magnitude. The responsibility to improve control of chemical hazards belongs both to Government and industry. While the chemical industry has taken steps to expand its capabilities to assess the toxicity of its products through the Chemical Industry Institute for Toxicology and other forums, there is a critical need for a systematic approach to addressing toxic substances. Such an approach would be a fundamental contribution of the toxic substances control legislation. Without a strong legislative mandate calling for concerted action by the Federal Government and industry in this field, the information needed to understand and to take responsible and effective action directed to the problem of hazardous chemicals will not be adequately developed. At the same time, we can no longer afford to continue to gamble with the unknown and to react to chemical crises only after the tragic effects are manifest.

AN APPROACH TO THE CONTROL OF TOXIC SUBSTANCES

Delivered by
Glenn E. Schweitzer
Director, Office of Toxic Substances

to the
National Association of Manufacturers
Annapolis, MD -- September 30, 1975

Recent Developments Concerning Toxic Substances

Hardly a week goes by that another chemical is not implicated as posing a hazard to health or the environment. While we are now accustomed to television and newspaper accounts of the problem related to industrial chemicals, last month even the lead article of Sports Illustrated was devoted to the resurgence of the problems associated with polychlorinated biphenyls.

I do not advocate using the press as a barometer for measuring the frequency or severity of chemical problems. However, there is little doubt that the list of more than 100 problem chemicals cited during the past four years of testimony on the Toxic Substances Control Act will continue to grow. The latency periods for the manifestation of effects of relatively new chemicals are drawing to an end. Monitoring programs are continuing to uncover previously unsuspected levels of environmental contamination. And the results of expanded toxicological investigations -- particularly chronic studies -- are showing an increasing range of effects for many chemicals.

Meanwhile, the efforts of Federal and State agencies, public interest groups, and industry to cope with these developments can only be described as chaotic. The Federal agencies, often relying on hastily collected and inadequately analyzed data, are straining to use existing authorities to address types of problems which were not envisioned as targets for control when the statutes were developed. As vividly demonstrated by the polychlorinated biphenyl problem, the use of existing authorities to shut off individual spigots of a multispigotted problem is often neither an environmentally effective nor a cost effective approach. Also, there are many important routes of environmental exposure associated with the manufacture, use, distribution, and disposal of toxic chemicals beyond the reach of existing authorities.

Another shortcoming of present Federal programs, despite the data collected by the Bureau of the Census and International Trade Commission, is the lack of information collected about uses and about by-products necessary to estimate likely chemical exposure patterns as envisaged under the proposed legislation. No authorities exist to obtain premarket information on new chemicals or new uses. And the narrowly focused testing authorities of the Department of Transportation, Consumer Products Safety Commission, and fuel additives section of the Clean Air Act cannot be relied upon to generate data useful in assessing many of the health and environmental effects of industrial chemicals that may be of concern.

Impatient Congressmen are introducing special purpose bills to cope with chemicals such as fluorocarbons on a case-by-case basis. Oregon, Illinois, Wisconsin, and other states are taking steps to curb toxic chemical problems of special concern to them. Public interest groups are accelerating their efforts to require EPA and other agencies to respond to the never ending series of chemical incidents, and it seems inevitable that very shortly the courts will become more deeply involved in setting standards for toxic substances. At the same time, industry is expanding its assessment activities directed to industrial chemicals through CIIT and other forums, hopeful but uncertain that the results of these efforts will be acceptable to the regulatory agencies. Also, industrial uncertainty remains high -- to say the least -- as to Governmental criteria for prioritizing toxic chemicals for attention, for assessing risks, and for balancing costs, risks, and benefits in reaching regulatory decisions.

The void in Governmental leadership in the toxic substances area -- an area wherein those who are exposed to the risks do not necessarily derive comparable benefits -- is glaringly apparent. However, in the absence of a strong legislative mandate calling for concerted action by the Federal Government and industry in this field, the necessary high quality resources will not be mobilized and applied. Without such a mandate the field will become even more chaotic and fraught with confusion in the years ahead. The scientific uncertainties and the economic stakes involved argue persuasively for the development and use of the best possible information -- information that is both authoritative and credible -- in decision-making in this area. Development of such information is the heart of the Toxic Substances Control Act.

The Toxic Substances Control Act should go a long way toward introducing an element of predictability, stability, and rationality into the overall approach to addressing toxic chemicals. Its emphasis on improved data for decision making would seem indisputable. Its requirement to explicitly balance risks and benefits in regulatory decisions is a welcome step to improved understanding by all as to the decision-making ground rules. And, of course, the call for the review of the health and environmental aspects of new chemicals before heavy investments are in place is designed not only to prevent avoidable incidents but also to minimize economic dislocations attendant to such preventive actions.

Economic Impact of the Legislation

Recent reports by industrial groups on the likely costs and economic impact associated with the legislation, and particularly the reports of Dow Chemical USA and of the Manufacturing Chemists Association, have frequently been cited as a basis for opposing the legislation at a time when the status of our economy is particularly worrisome. However, let me cite several examples from these reports which illustrate some of the serious questions that have been raised as to the usefulness of the reports and the reliability of their projections.

First, it has been estimated in one of these reports that about $1 billion would be lost to industry each year due to regulatory actions which result in the abandoning of the equivalent of 48 industrial facilities valued at $20 million each. The clear implication is that uncontrolled industrial chemicals are currently causing widespread environmental damage -- damage so extensive that after consideration of both the environmental risks and economic benefits associated with such chemicals, an annual cost of $1 billion for corrective action by industry would be warranted. It apparently is further assumed that in taking corrective action under the proposed legislation, industry could not recover any of the facilities for any other purpose nor recoup any of the losses through amortization, tax, or other financial arrangements. In addition, no allowance is made for substitute products which might be introduced by the affected companies or by other companies to fill the voids resulting from regulatory actions. These assumptions are difficult to accept.

As a second example, it has been assumed that EPA would require comprehensive testing, such as is currently required for registration of pesticides, for each significant new chemical innovation. The cost to industry of such comprehensive testing is estimated at over $700 million annually, after allowing for the testing that would be conducted by industry in the absence of the legislation. I consider this assumption to be unrealistic and inconsistent with the intent of the legislation. In considering testing requirements, pesticides do not provide a good analogy. They are deliberately toxic and are deliberately dispersed widely into the environment, including dispersal on food sources. Thus, the need for extensive testing is clear. Industrial chemicals are not usually developed because of their toxicity properties nor are they usually intended to be placed in the food chain. In recognition of these differences, the concepts of registration and certification for industrial chemicals have been repeatedly rejected by the Administration and the Congress.

Next, it has been estimated that one company would be required to hire an additional 75 to 100 regulatory experts, lawyers, knowledgeable professionals, and support personnel to prepare information for EPA, to answer EPA questions, and to interpret regulatory requirements. In addition $1 million annually would be required to keep abreast of EPA's intereactions with other regulatory agencies. These estimates appear to be high.

Also, it has been estimated that in order to maintain the current rate of innovation within the chemical industry after the Toxic Substances Control Act is in effect, up to $600 million annually must be added to the industry's current R&D budget to offset new R&D costs associated with the more complex commercialization cycle and with testing and other compliance costs. In addition, it is estimated that up to $530 million annually would be required to cover costs associated with premarket screening, premarket delays, testing, and other related costs. The report provides little basis for the $600 million estimate, and there appears to be considerable overlap between the two types of costs. In the absence of access to the data base, we are very uncertain as to the validity of these estimates and the extent of the double counting that might be involved.

With regard to estimates concerning regulatory actions, the incremental costs of using more expensive substitutes in place of chemicals that are banned has been identified as a major cost element. As a case in point, the impact of a ban on the use of PCBs in closed electrical systems has been estimated. However, this is precisely the use which has usually been excluded from recommended limitations on PCBs because no adequate substitutes were available. Thus, in effect a "worst case" and probably unrealistic example has been chosen as a basis for estimating the costs of regulatory actions.

Finally, the estimate that implementation of the Toxic Substances Control Act would result in unemployment rates of 20,000 to 80,000 annually is difficult to understand. Not only are these predictions far beyond the sensitivity of the model that was used but are inconsistent with the programmed rate of the model. In this regard spokesmen for the AFL-CIO have indicated that an impact of 1,000 was a reasonable estimate.

Meanwhile, the claims of environmental groups that the cost of a testing requirement could be as low as a few hundred dollars seem to neglect the realities of today.

Given these extreme positions, we have felt obligated to make our best estimate of likely impact. Therefore, despite our reservations concerning the highly speculative nature of such projections, five months ago we set forth our estimate that the annual cost to industry associated with implementation of the legislation. According to our estimates, the cost impact would be on the order of $80 to $140 million annually -- or between one and two percent of the net profits after taxes of the affected sector of industry. Of course, the impact would not be spread evenly, with some companies affected to a greater degree and others to a lesser degree. After reviewing information that has been developed in recent months, we continue to believe that our estimate is reasonable.

The Character of the Legislation

Now turning to the specifics of the legislation, let me comment on several provisions of particular interest to you.

-- The legislation should explicitly require that in taking regulatory actions under Section 6, consideration will be given to the impact of the actions on business, employment, and the economy.

-- The legislation should clearly separate premarket notification requirements, which should encompass all chemicals produced in commercial quantities, from more circumscribed authorities concerning premarket screening, which might be more accurately described as Governmental intervention during the premarket period.

-- A proposed rule during the premarket period limiting the production or use of a new chemical under Section 6 should not become immediately effective. The likely environmental benefits which would ensue do not appear to warrant this abridgement of due process prior to completion of the rulemaking process.

-- The concept of lists, in the context of either premarket or testing requirements, would only add confusion and delay to responsible implementation of the law. If a chemical warrants regulatory attention, a two-step process is unnecessary. In addition the list concept would inevitably result in unnecessarily implicating listed chemicals which do not subsequently become the subject of regulatory actions.

-- Comprehensive annual reporting on all commercial chemicals is not of sufficiently high priority to warrant the cost to industry and Government which would be required to conduct an effective program. Therefore, the legislation should not make this a mandatory requirement but rather provide EPA with discretionary authority to require annual reporting as needed.

-- Similarly, the requirement for mandatory comprehensive reporting of all health and safety studies conducted by industry during the past 40 years should be replaced with discretionary authority for EPA in this regard.

In conclusion, I would simply stress that recent events have confirmed the need for this legislation. The existing legislative framework does not provide an adequate basis for sound environmental decisions. Nor does it provide the focal point for national leadership so urgently needed in this field.

NEEDS OF THE ENVIRONMENTAL PROTECTION AGENCY FOR MUTAGENIC ASSAY DEVELOPMENT

Delivered by
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to the
National Center for Toxicological Research Science Advisory
Board Subcommittee on Mutagenesis at N.C.T.R.
Jefferson, AR -- September 29, 1975

The Environmental Protection Agency functions under a series of laws which gives us the broad responsibility for protecting human health, non-human species, and the physical environment from chemicals which are released into the environment due to human activity. In general the Agency itself is responsible for obtaining the data required to justify it's regulatory activities. Thus, for most air or water pollutants which may come into contact with humans, the EPA would have to perform the research required to assess toxicity. This is done through a research program conducted both in EPA laboratories and through grants and contracts.

There are two specific areas in which EPA has the authority to place the burden of testing for human health effects upon the manufacturers of chemicals. These areas are pesticides and fuels and fuel additives.

Every formulation of a pesticide shipped in interstate commerce must be registered with the Environmental Protection Agency. The granting of a registration for a pesticide formulation is dependent upon the submission of adequate safety data by the manufacturer of the pesticide or formulation. There are over 30,000 such pesticides formulations currently registered containing over 1000 pesticidally active ingredients. Three to four hundred of these active ingredients are used in such a way as to make contamination of food or animal feed likely, and for these pesticides the EPA must establish tolerances or allowable concentrations in the food or feed. This past June the EPA proposed regulations stating that mutagenicity testing will be required for the registration of all pesticides requiring food or feed tolerances or otherwise significantly contaminating the human environment. For pesticides which are already registered, this proposed mutagenicity requirement would be implemented in a phased manner over a five year period from 1977 through 1982. For pesticides which are not currently registered, initial registration would require mutagenicity testing. The exact nature of such testing is at this point unclear and is a matter of serious concern within the Agency.

The Clean Air Act of 1970 gives the Environmental Protection Agency the right to require manufacturers of fuels and fuel additives for motor vehicles to register these products and to test them to determine potential public health effects. The EPA has not yet implemented the testing requirement authority granted by the law due in part to the great complexity of the fuel additives problem. When a manufacturer wants to add a particular additive to gasoline, it is not only the toxicity of the additive which is of concern but also the toxicity of the combustion products of the additive and the toxicity of any new combustion products from other components of the fuel which may be formed due to the presence of the new additive. Of course, combustion products vary not only with fuel composition but also with the properties of the engine and the development of protocols for toxicological evaluation of fuel additives is correspondingly complex.

In addition to its authority over pesticides and fuels and fuel additives, the EPA may be granted a much broader authority to require industrial testing of chemicals if the Toxic Substances Control Act is enacted into law. This act would extend EPA's authority to require such testing to virtually all industrially produced chemicals except for food additives and drugs. There are probably more than 10,000 chemical compounds currently in commerce which may come under the authority of the proposed legislation with several hundred new ones added each year.

It is interesting that many of the laws under whose authority EPA acts, including the proposed Toxic Substances Control Act, specifically mention mutagenicity as an area of Congressional concern and EPA's regulatory authority.

EPA'S CURRENT WORK IN MUTAGENESIS

I would now like to briefly review EPA's current activities in the area of mutagenesis. Since EPA is organized more along the lines of legislative authorities than by scientific disciplines, there is no central office or laboratory responsible for mutagenesis work and my list of EPA's activities may be somewhat incomplete.

Four contracts for mutagenicity studies have been let as part of the EPA's Substitute Chemicals Program, which is an activity of EPA's pesticides and research offices. In the first contract, the group at Washington University in St. Louis led by Barry Commoner has been studying the correlation between carcinogenicity and mutagenicity in Salmonella typhimurium. This is being done by testing the mutagenicity of 50 known mammalian carcinogens and 50 chemicals generally believed to be non-carcinogenic.

A series of so-called "substitute pesticides" is being evaluated by several mutagenicity tests at the Stanford Research Institute and the WARF Institute in Madison. The Stanford Research Institute has been using the Ames Salmonella test, mitotic recombination in yeast, unscheduled DNA synthesis in human fibroblasts and dominant lethal testing in mice. The WARF Institute has been looking for sex-linked recessive lethal mutations and chromosome breakage and loss in Drosophila treated with the pesticides. It should be noted that there resulting from drinking water treatment. A contract with the Stanford Research Institute in progress to study the mutagenicity of 32 organic chemicals which have been or may be found in drinking water. These compounds will be tested both before and after treatment with ozone, since ozone is the most liikely alternative disinfection method if chlorination turns out to be causing serious problems. The indicator organisms used will be the Ames tester set of Salmonella and Saccharomyces cerevisiae strain D3. In addition, samples of actual sewage effluent resulting from several types of disinfection processes will be studied. The samples will include effluents disinfected by chlorination, chlorination followed by dechlorination with sulfur dioxide, ozonation, bromochlorination, and an untreated control.

A group at Louisiana State University led by Dr. William Pelon has been studying the mutagenicity of Mississippi River water using the Ames system.

The only ongoing in-house mutagenesis program in EPA involves the assessment of a series of inorganic chemicals found in drinking water utilizing the BUDR-visible light isolation technique with Chinese hamster ovary cells. Thus far compounds of arsenic, beryllium, cadmium, cobalt, nickel, and selenium have been tested with cadmium and beryllium tentatively giving positive results and all others being negative.

In general the problems faced by the EPA in the area of toxicological testing are the same as those of others concerned about human exposure to chemicals. Problems which are particularly severe at EPA, however, include: too many chemical to test; too little information about human exposure to each chemical; and the fact that many chemicals in the human environment remain unidentified.

I have tried to break down the types of chemicals which should be subjected to toxicological, including mutagenic, evaluation into three categories.

The first category would be single chemicals with known structures to which human exposure is high. In this category we might place the 3-400 pesticides which are permitted to leave measurable residues in food. We might be able to put some high-priority widespread drinking water contaminants in this group as well as some of the major air pollutants such as sulfur dioxide and oxides of nitrogen. A few so-called trace contaminants such as polychlorinated biphenyls would also fit into this category. These chemicals obviously should be subjected to a reasonably thorough mutagenic evaluation in a variety of test systems.

The second group of chemicals includes those with known structures to which human exposure is thought to be relatively low. These would include registered pesticides for which food tolerances are not required, most organic chemicals which have been identified in drinking water, and those air pollutants which tend to be localized or infrequent, such as those emitted by small or unusual industrial processes. For this class of chemicals it is clear that some sort of prescreen is necessary since the resources for a thorough mutagenic evaluation will clearly not be available. Such a prescreen would serve two purposes. First, it would help us set priorities for which chemicals should be subjected to a more complete test regimen. Secondly, it might help us make initial judgments which can lead to a stronger or weaker regulatory response to other possible problems asociated with the chemical.

The third class of chemicals which EPA has to deal with are those environmental mixtures whose chemical identity is not firmly established and which can vary greatly with time. This includes over 90 percent of the organic matter found in drinking water, much of the particulate matter in air, and effluents from most industries and all sewage treatment plants. We also face the problem that the environmental metabolites of pesticides and industrial waste products may be unknown and it is these metabolites to which humans are likely to be exposed rather that the parent compound. There are obviously serious difficulties associated with testing uncharacterized mixtures and drawing meaningful conclusions from test results.

Each of the three categories of chemicals I have mentioned may require a different approach to mutagenesis testing. Thus each cateory raises somewhat different problems as to current research needs.

For the first category, the known high-exposure chemicals which should be subjected to thorough mutagenic evaluation, the basic need is for sensitive reliable indicators of mammalian mutagenicity capable of detecting a broad spectrum of genetic events. The most urgent problem in this area would seem to be the development of a sensitive assay for heritable point mutations in whole mammals in which mutations in a large fraction of the genome can be detected. While development of such systems is in progress, their general availability is at best several years off. In the meantime it may be necessary to depend on test systems which do not directly measure heritable mutations in whole mammals. If results from such systems are properly evaluated in the light of pharmacokinetic data derived from whole mammals, convincing arguments for regulating a chemical as a mammalian gene mutagen might be made. This points up the need for the perfection of more routine procedures to demonstrate the presence of the active form of a mutagen in the germinal cells of whole mammals and the reaction of these compounds with germ cell DNA. While there are practical reasons for developing such methods in male animals, the demonstration that a possible mutagen does not reach the testes cannot be considered convincing evidence of non-mutagenicity in the absence of corresponding data in female animals. Thus the development of pharmacological techniques for mutagens in male animals alone will still leave us unable to make knowledgeable health judgments and regulatory decisions.

The second category of environmental chemicals which I mentioned includes those thousands for which human exposure is thought to be at low levels or infrequent. The obvious need here is for the development and validation of prescreens. If rapid, relatively inexpensive, and reproducible tests for mutagenicity could be validated against those tests thought to be more relevant indicators of mammalian mutagenicity, we would then know the usefulness of these tests for prioritizing chemicals for further testing. If we had a good idea of the rate of the so-called "false positive" and "false negative" results which the prescreen gave for various chemical classes, then we would also be able to estimate the degree of concern which might be warranted by positive results in the prescreen before more comprehensive testing is completed. The most serious problem in the development of prescreens at this time appears to be the lack of suitable methods for detected chemicals which cause only chromosomal mutations. The limited range of genetic events currently detectable at the prescreen and at the whole mammal level makes an increased understanding of the correlation between chemical induction of gene mutations and of chromosomal aberrations quite important. Similarly, it would be important for us to understand whether any chemical mutagens can act uniquely at meiosis and, if so, to develop prescreens capable of detecting such mutagens. A greater understanding of the relationship between chemical structure and mutagenic activity would help enormously in selecting those chemicals to be subjected to the prescreen or at least those which should be screened first.

In general the third category of chemicals, those mixtures which have not been characterized, will require a prescreen type of evaluation as well. The use of mutagenic prescreen techniques may in fact, help us to isolate those components of uncharacterized mixtures which pose the greatest mutagenic or carcinogenic hazard.

There has been great deal of concern expressed about the need to develop methods for quantitating the mutagenic potency of chemicals. We must be careful not to divert too many resources to quantitation when methods for identifying qualitative mammalian mutagens remain to be developed and validated. We may find ourselves in the position of making quantitative risk estimates for mutagens based upon one type of genetic event when the agent in question is capable of producing other types of mutations which we are incapable of detecting. This could lead us to seriously underestimate risks.

Let me mention two problems in mutagenicity testing which may be unique to the needs of the Environmental Protection Agency.

The first, which I have already alluded to, is the fact that people may be exposed not to the chemicals released into the environment, but to a metabolite which is created in the environment. The questions that have been raised recently concerning the mutagenicity of corn metabolities of atrazine and the possible presence in drinking water of N-nitroso compounds, possibly including derivatives of pesticides, cannot be ignored. Perhaps we will have to develop environmental activating systems to supplement our mammalian activating systems. These might include terrestial plants, aquaria, or systems inoculated with sewage sludge.

The second problem unique to EPA stems from our responsibiity for protecting both environmental health and human health. I am not aware of any evaluation of the possible impact of chemical mutagens on natural populations of plants and animals. The type of analysis necessary for natural populations is fundamentally different than that required for humans, in that we are concerned about each individual case of human disease or disability, while for natural populations we are concerned only about the continued survival and functioning of the species. I would like to know, for example, whether there are species which would not have the capacity to survive and function normally if the mutation rate were to increase by a factor or two or five or ten.

One of the most difficult problems which regulatory agencies have to face in dealing with toxic chemicals is the continuing question of whether or not those chemicals which are toxic to animals are also toxic to humans? If anything, this problem will be more serious for mutagenesis than for carcinogenesis because the long time lag between exposure and effect apparently causes many people to have serious difficulty in understanding the significance of mutagenesis to humans. Particular effort should be devoted towards the understanding of the correlation between heritable mutagenic effects and chromosomal aberrations in peripheral lymphocytes since this is the one area in which observations can be made directly in humans.

In view of the primitive state of the art in most areas of mutagenicity testing, the uncertain relevance of many assay systems to heritable effects likely to occur in man, the lack of experience with a wide spectrum of chemical classes for many of the assay systems, and the tremendous potential for harm which chemical mutagens in the environment may have, it is impossible to be very specific as to what areas of research are the most important. Research on a broad front is obviously needed and we must be careful not to stifle basic research which will ultimately help us to deal with some of the problems we now face. Among the high priority items for the next few years, however, would be: (1) a broadening of the chemical data base for existing test systems supplemented with suitable metabolic activation techniques so that we can make more rational judgments as to the utility of these systems for testing a wide range of chemicals, (2) the development of systems which can detect mutagens capable of causing point mutations in whole animals with far greater sensitivity than methods currently available, and (3) the development of chemical methods for studying the interaction of mutagens with germ cell DNA in both male and female animals.

ENVIRONMENTAL ASPECTS OF CHEMICAL USE IN PRINTING OPERATIONS

Delivered by
Farley Fisher, Ph.D.
Branch Chief for Early Warning

to the
Conference on Environmental Aspects of Chemical Use in Printing Operations
King of Prussia, Pennsylvania -- September 22-24, 1975

Opening Comments

I would like to welcome you all to the opening of the conference on Environmental Aspects of Chemical Use in Printing Operations sponsored by the Office of Toxic Substances of the Environmental Protection Agency.

I am Farley Fisher, Chief of the Early Warning Branch of the Office of Toxic Substances of EPA. I am going to be your general chairman here, which means I am pretty much of a figurehead.

However, since I am largely responsible for setting up this snowball, which has developed into this conference, let me say just a few words about why we decided to hold this conference and what we hope to accomplish.

The mission of the Early Warning Branch in EPA basically is to identify potential environmental problems and to try to achieve some sort of study and, if possible, some sort of resolution of those problems before the matter becomes one of general concern and has to be settled in an arena where speed is of the essence, where frequently, rational thought and careful consideration get sacrificed in order for things to be done rapidly.

As part of our attempt to accomplish this, we thought, about 2 years ago, that it might be nice to look at a few industries where people seemed to have the feeling there were a lot of things going on, but nobody really knew what. The idea was to find out exactly what the problems are or if business is just a lot of rumormongering and in fact, the problems are not nearly as severe as many uninformed people seem to think they are. Accordingly, we set up a series of conferences, which we hope will be a continuing series. We invited people who are knowledgeable, who have things to say, to come to a public forum which would be organized in such a way that all persons, including those not on the program, would have an opportunity to contribute what they could so that we could get a reasonably good picture of exactly what the situation in question is.

Somewhere along the line we abandoned the notion of holding conferences by industries and felt that it would make more sense to

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do it in terms of a series of processes without necessarily identifying them with industries, even though in many cases the correspondence would be rather close. Consequently, this conference is on printing processes. We hope to discuss any printing operation, regardless of the type of industry to which it is nominally attached.

This is the third conference in the series. I think the series has been successful at what we hoped it to do. These conferences have shown that they can, in fact, stimulate a lot of good discussion and stimulate people to do some thinking about things they might not otherwise have considered.

It is inevitable when you hold a meeting for a general audience that many of the people find some of the matter presented rather elementary while others consider it quite new and interesting. I anticipate that most of you, at one time or another, will feel bored by the presentation on the grounds that you have heard it before. But I also think very strongly that every one of you will find a great number of papers that will in fact tell you things that you did not know before. I certainly hope every one of you goes away from here knowing something you did not know when you came.

I want to make it clear that this is not a witch hunt. This is not an attempt to put the printing industry behind the eight ball. There are no regulatory actions which are expected to stem, in a direct sense, from this conference.

I want to encourage everybody to be open and candid in what they have to say because I think that is the only way we are going to accomplish what we are here to do.

The emphasis in this conference is on the environmental aspects: the external environment, including air and water pollution, waste-disposal problems, and matters of this nature. We realize that it is very difficult if not impossible, to separate the environmental concerns from what you might call microenvironmental concerns, the occupational setting, and some of the papers today will in fact deal with occupational studies. We consider this quite appropriate. However, it is my hope that we do not allow this to turn into a conference on industrial hygiene. The idea of the conference is to discuss the environmental aspects of chemical uses.

Mr. Frank Ayer, who is standing by the door there, is the conference coordinator from Research Triangle Institute. He and his staff are available to help you with your problems. If you have any questions, please seek him out. You will notice he already has grey hair, so you are not going to hurt that too much more.

We are trying something a little bit different in this conference from what we have done in the past. Because this is a general audience and we realize that the industry itself is broken into some rather specialized components, we are going to start with a brief review of practice in printing operations. This review is based on a technical study, which was performed by RTI as a planning step in designing this conference. In the past, we have not presented the results of this study at the conference itself, but we have found that this frequently meant that speakers who really wanted to talk at a technical level had to go back and give a primer to much of the audience about what they had to say. This study, I realize is going to be old news to those of you who are experts in the field, but we hope, by presenting it, to bring some of the nonexpert audience up to a level that will permit the other speakers to launch right into technical material.

SESSION IV: IMPACT OF NEW DEVELOPMENTS AND CHEMICAL FORMULATIONS

Opening Comments

Our final session is on the Impact of New Developments and Chemical Formulations. It was with considerable pessimism that I originally accepted the idea that we should try to hold a session on new developments. My first reaction was, "Who is going to want to talk about something that they are trying to keep under their hats until they are ready to sell?"

I must say that I have been very gratified by the response from the industry. We do have a number of people here who are going to talk about some relatively new techniques and methods, which may offer real advantages from the point of view of environmental control.

CONFERENCE SUMMATION

This concludes our conference. I hope you have all learned something: maybe not as much as I have, but I hope you have all found it profitable.

Before we close, I would like to express my appreciation to our four session chairmen: Dr. Burachinsky, Dr. Schaeffer, Mr. King, and Mr. Downie; and to our roster of speakers who I think have done a very nice job of presenting us with an awful lot of material. I would also like to thank all of you who attended, who participated from the floor, asked questions, and made comments. I would like to thank the staff of the Holiday Inn, Valley Forge, for their cooperation and the facilities they provided us, and the Montgomery County Convention and Visitors Bureau for their assistance in manning the registration desk and helping some of us out with some arrangements. I owe thanks to a few organizations who gave us considerable assistance in putting this program together: the Graphic Arts Technical Foundation, the Gravure Research Institute, the Association of Photographic Manufacturers, the National Association of Printing Ink Manufacturers, and the Printing Industries of America.

At this point, I am supposed to give some general summation and impressions from the conference. This is always very embarrassing because I am told that I am to summarize a conference, but I am not to say anything that might be interpreted as a government policy. So, I have to make that caveat and say that I am speaking for myself. I am not the kind of person who can sit here for 2-1/2 days and immediately have everything figured out and know exactly what it all means. I have to go home and sit down with the record and think about a lot of the things I have heard.

I do have just a couple of general impressions that I will share with you. One is that I really have the impression, Dr. Muggli's comment notwithstanding, of an industry which, at least on the surface, is really quite innovative. It is not an industry that is opposed to new techniques and new ways of doing things. This impresses me because I know of a lot of industries of which that simply is not true. I think that this innovation holds out a very great promise, but we have to remember it also carries with it an attendant risk. This is true environmentally as well as economically. Every new advance is somewhat untried. No matter how much we worry about it, no matter how much thought and commiseration and debate we have, whenever something new really comes into use we find out things about it we just did not know before.

And so we do have to keep our guard. We do have to take all the care we can. And we really have to trust a little bit to luck if we are going to improve, to make a better future and not a poorer future for ourselves and the people who follow us.

I also have the feeling that the industry is at least aware of some of its problems, and those it is aware of, it is making a serious attempt to deal with.

It is also very instructive that we have learned that people who made environmental improvements as recently as 5 years ago, despite the advice of their bankers that it was a waste of money, have found themselves coming out smelling very nice in the money market. This tells us something that I think any third grader knows but which we tend to forget when we grow up; namely, that waste is waste.

All this stuff that EPA, the various States, and other people are complaining about dumping in the environment because they don't like it there is in many cases useful stuff. Throwing it away is just not a commonsense thing to do. We have to make an effort. After all, the best way to deal with waste is to realize that it need not be a waste, that maybe it is a useful commodity in its own right. I think we have seen some very good examples of that here, and I hope that we can keep on moving in this direction.

I've probably said enough for the time being. Before I adjourn the meeting, however, I would like to open it up for comments from the floor for one last time, in case anybody does have something they have not had a chance to say up to now.

Mr. Frederick Wootton (Prince George's County Health Department, Cheverly, Maryland): I have sat here for 2-1/2 days and have enjoyed it. I don't know if I really have enough information to put out. Sixty-five percent of all your taxes are going to the military. I should point out that, being a health person, I believe that possibly we could divert some of these funds to some of the research that you all have said has cost you so much.

Mr. David Friedman (Food and Drug Administration, Washington, D.C.): We have heard several comments by some speakers that there is an adversary atmosphere between industry and the various government agencies, and that there should be more cooperation. I want to suggest to everyone that the relationship need not be antagonistic; we are not out to "get" anyone. If industry and trade organizations would cooperate, would give us the information we need -- before new developments are in progress, when new techniques are being developed -- if they would work with the various environmentally active agencies, industry might be able to find out what not to do. It is a lot easier to reformulate before environmental damage, or before commitment in the marketplace, than it is afterwards. We are out to try to prevent problems, and not simply deal with them once they are known to exist.

Mr. Theophilus R. Carson (Food and Drug Administration, Washington, D.C.): I would like to commend Dr. Fisher and Mr. Ayer for the wonderful job they did in getting this together as fast as they did. I had to take someone else's place; that is why I am here.

Mr. Al Jasser (Anchor Chemical Company, Hicksville, New York): I want to commend you, Dr. Fisher, for the conference. I have one plea from industry. The problem you have stated at another time was that there is not communication. This young man from FDA again repeated that there should be cooperation. Industry is always willing to cooperate with government if it can understand what government wants. If the language in the Federal Register, for example, were such that my staff could understand it without lengthy conferences, we would be well along in the way of cooperation. We are very happy to cooperate. Is there something that you can do in seeing to it that the directives, orders and prospective regulations are in clear, simple language so that we in business don't have to take a special course?

General Chairman Fisher: I would point out to you, first off, that I am a chemist myself; most of the government people here, I imagine are technical people of one type or another. Most of the industrial people here, I imagine, are technical people of one type or another--engineers, chemists, and so on. But the fact of the matter is that the government is run by lawyers. They write the Federal Register. Business is not really run by scientists and engineers either. Business is run by businessmen. I think all we can really strive to do is maintain communication at the technical level so that we at least know what we are supposed to be doing. I know it's just a plain fact of life that when you get into the higher levels of management in either government or industry, a lot of information can be obscured.

I would like to make one more comment which I have heard made privately on a number of occasions. Dr. Shaeffer and I have discussed it at some length. That is, many of these engineering advances that we have heard discussed here, many of the fancy pollution control devices, are really practical only in large installations. But, in fact, we are dealing with an industry which has an awful lot of small installations. In a sense, we have been a little unfair, because I really do not think we have addressed the problems of these small operators. Many of the things which we did discuss are not practical from their point of view. I think that is an area which requires more thought and a little more effort.

If there are no further comments, I will call the meeting adjourned. I want to thank you all for your cooperation and attendance.

ENVIRONMENTAL LEVELS OF PCB'S

Delivered by
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Branch Chief for Monitoring and Information Systems

to the
International Conference on Environmental Sensing and Assessment
Las Vegas, Nevada -- September 15, 1975

ABSTRACT

Since the 1966 discovery in Sweden that chlorinated biphenyls were widely dispersed in the environment, their environmental levels have been the subject of many studies with the results indicating that PCB's can have adverse ecological and toxicological effects. However, a well planned national approach to environmental sampling has not been attempted, thus hindering making a national assessment of the PCB problem. This paper reviews the levels that are currently being found in the environment.

INTRODUCTION

Since the 1966 discovery in Sweden that chlorinated biphenyls were widely dispersed in the environment, their levels have been the subject of many studies both abroad and in the United States. Extensive laboratory and environmental measurements indicate that PCB's can have adverse ecological and toxicological effects, are very resistant to environmental degradation, and are being discharged by many different sources.

This paper will focus on the current PCB data base in an effort to assess the PCB levels in the environment on a national basis.

ENVIRONMENTAL PCB SOURCES

Before the PCB data base is examined, it would be of interest to review how these chemicals get into the environment. The major sources contributing to the environmental levels of PCB's are industrial effluents, manufacturing processes, consumer and industrial waste materials, sewage treatment facilities, and accidental spills. Lacking extensive air and soil data from these sources, available water data are shown in Table 1. The 5 major PCB spills in 1973-75 all involved transformers. In 4 of those incidents, the PCB's were spilled on soil while in the fifth the transformer was dropped on a pier and the contents were spilled into the water. In the latter incident, 283 gallons were spilled. and it was estimated that only 70-90 gallons were recovered. In all cases the material that could be recovered was drummed up and entombed at a cost approaching $2.3 million.

REVIEW OF THE PCB DATA BASE

To assess the scope and extent of PCB's in the environment, all national surveys and national data bases maintained by the U.S. Environmental Protection Agency (EPA) were examined, including STORET, the national water quality storage and retrieval system, the National Soils Monitoring Program for Pesticide Residues, and the Human Monitoring Program. In addition, data from special data bases maintained by the United States Geological Survey and the open literature were also examined along with available unpublished reports. Using these data, maps were constructed showing the concentrations of PCB's in urban soils and the aquatic environment.

The data from the national surveys show that a great deal of effort has been expended and continues to be expended, but that the data are very limited. On examination, all States are believed to show some level of PCB contamination. In Table 2, States which had significant levels in at least one medium are listed with their reported PCB levels for surface and ground water, bottom sediments, and fish. In Table 3, a number of localized studies are listed along with the reported environmental data. In all these studies the most extensive measurements have been in fish.

WATER

On the basis of the national aquatic environmental data collected in 1971-1972 and in 1974, a continuing widespread accumulation of PCB's in water, sediment, and fish appears to be occurring. However, no trend analysis is possible with the available measurements. For example, whole water measurements have been taken throughout most of the country, but those states reporting non-zero readings are few in relation to the number of states showing zero concentrations. This is due both to the low solubility of PCB's and to the usual analytical procedure that limits detectability to the 0.1 ppb level. More meaningful water concentrations were obtained in the Lake Ontario[1] and Orange County, California[2] studies where concentrations in water at the ppt (ng/l) level were measured. At these levels, changes in PCB concentrations could be found with distance and time and could be related to other measurable parameters, such as PCB concentrations in sediment, flora, and fauna.

SEDIMENTS

Since PCB's are relatively insoluble, it is not surprising that bottom deposits have shown significant concentrations. Although 30 states collected samples in the 1974 study, 15 had less than 4 stations reporting and showed zero readings. Of the remaining 15, with at least 4 reporting stations, 13 showed detectable concentrations. Since the 13 states involved were not necessarily the same in both studies, only a very broad conparison may be made, i.e, five states had lower concentrations, four states were higher, and four did not sample again[3]. We may conclude, then, that in those states with any monitoring effort in the 1974 study, PCB's are present in bottom deposits and the levels are not any lower than in the 1971-72 study. Considering the persistence of PCB's, a significant proportion of the nation's waters are now affected and will continue to be.

SOILS

The National Soils Monitoring Program is a small sampling effort studying only 5 urban areas each year. However, PCB's were detected in three of the five cities sampled in each of the years for which data are available, 1971-73. Of the 22 positive readings, 17 of them were below 1 ppm. Of the cities sampled in 1973, Pittsfield, Mass., was of particular interest because it has a large transformer and condenser plant using large quantities of PCB's. Six different sampling sites within one mile of the plant show no detectable PCB residues. In contrast, the soil surrounding another facility in Illinois using PCB's in the manufacture of investment casting waxes was recently measured for PCB content. Samples taken in an area one-quarter mile radius around the plant ranged in value from 0.77-5.2 ppm. The PCB's identified were mixtures of Aroclor 1260 and decachlorobiphenyl. Levels up to 1.8 ppm Aroclor 1260 were found at 1-1/4 miles from the plant. Samples were collected from this facility as part of a study being conducted for the Office of Toxic Substances at sites suspected to have PCB concentrations. Other sites sampled in March of 1975 were in the vicinity of an investment casting company in Michigan and the PCB manufacturer in Illinois. Surface soil samples were collected at each site up to a distance of approximately one mile from the plant boundary, at 1/4 mile intervals in all directions. PCB's were detected in soils at both sampling locations. Concentrations ranged from the detection limit of 0.001 ppm to over 20 ppm. The distribution of all PCB's analyzed appears higher near the plant site and generally decreases with distance from the site.[4] Details of the sampling sites and the concentration levels measured are shown in Figure 1.

AIR

PCB measurements in air along with the related transport studies are practically nonexistent. Harvey and Steinhauer[5] have reported levels ranging from 3.9 - 5.3 ng/m^3. Air measurements by Bidleman and Olney for Rhode Island ranged from 2.1 - 9.4 ng/m^3 and from 0.21-0.65 ng/m^3 at Bermuda.[6] Snow melt water data from Wisconsin ranged from zero to 0.24 ppb. The suggestion has been made that atmospheric fallout may be the most significant source of PCB discharge to the waters of the state of Wisconsin.[7]

FISH

Fish have been studied on a nationwide basis by the Department of the Interior since 1967. In the 1969 study, PCB levels were identified in fish from 35 states.[8] Data from the nationwide sampling programs, 1970-1973, are currently being prepared but were not available for this report. Consequently, nationwide fish data are not available any more currently than 1969, with the exception of the isolated studies listed in Table 3. The 1969 national study showed PCB levels generally within the FDA 5 ppm guideline. In the Great Lakes area, PCB levels in fish from Lake Michigan were so high, 7.6-10.9 ppm, that FDA seized shipments of coho salmon in May 1975.[9]

Although transport mechanisms are not well known and would vary through different ecosystems, it is interesting to consider the Lake Ontario Ecosystem Study summarized in Table 4. From this study an estimate of biomagnification is possible giving a sediment to fish ratio of 1:120. The FDA guideline of 5 ppm in the edible portion of fish corresponds to a sediment concentration of 41 ppb-a figure exceeded in all 13 states reporting through USGS in 1974.

HUMANS

With PCB's as widespread across various media as they are, it is expected that levels would be identified in humans as well. The Human Monitoring Program, in 1972, found that 3,035 out of 4,102 samples from 31 States showed levels ranging from less than 1 ppm to more than 3 ppm. In 1973, 964 out of 1,277 samples from 28 States again showed levels in the same range. In both years approximately 75 percent of the adipose tissue analyzed contained some polychlorinated biphenyls. Unfortunately we do not know age, occupational, or residential histories of the cases involved, so it is difficult to trace the levels back to the potential sources.

CONCLUSIONS

Although there are many national and state groups collecting environmental PCB data, limitations in the current data base prevent one from making a uniform national assessment of PCB environmental levels. It appears that if a well planned national approach to sampling were attempted, the data base could be improved in a very short period of time.

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TABLE 1
ENVIRONMENTAL SOURCES OF PCB's

Source	Effluent Water Concentrations (ppb)
PAPER MILLS	
Wisconsin[1]	0.1 - 18.5
WASTE PAPER MILLS	
Wisconsin[1]	18.5
INDUSTRIAL EFFLUENTS	
California[2]	0 - 76
Wisconsin[2]	.04 - 0.25
Ohio [2]	0 - 17
Michigan[3]	.1 - 7000
MUNICIPAL WASTE WATER TREATMENT PLANTS	
Michigan[3]	0.5
Wisconsin[1]	.05 - 17
Ohio [2]	10 - 17
California[2]	0.16 - 76
CAPACITOR AND TRANSFORMER FACILITIES	
New York [4]	2800
Massachusetts [5]	42.5
PCB MANUFACTURING FACILITY	
East St. Louis [5]	.87
SPILLS	Variable

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TABLE 2
SELECTED STATE DATA ON ENVIRONMENTAL LEVELS OF PCB'S

State	Surface and Ground Water[1] µg/l	Bottom Sediment[1] µg/kg	Fish[3] ppm
AL			1.53-5.48
AR		20-2,400	1.69-3.88
CA	0.1	20-190	
CO	0.3		
CT	0.1-0.2	5-350[2]	2.16-5.34
FL	0.1-2.1	5-3,200	0.10-1.25
GA		10-1,300	0.52-1.18
IL			1.21-11.3
IA			0.35-1.41
MD	0.1	10-1,200	0.56-1.31
MA	0.2		
MI			4.00-11.7
MN	0.1-0.3		0.44-1.09
MS		50-170	
NB			0.47-4.58
NJ	0.1	3-800[2]	0.10-4.00
NY	0.1-4.0	3-13,000[2]	2.68-9.50
OH			1.73-8.07
OR		1-5-140	0.71-3.62
PA	0.2	6-700[2]	1.94-2.48
PR	0.1		
SC		30-200	0.10-7.3
TX	0.1-3.0	7.9-290	0.10-0.22
UT			0.15-2.14
VA	0.1	5-80	
WV		10	0.31-1.20
WI			1.24-14.8

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TABLE 3

SELECTED PCB STUDIES

Lakes	Fish (ppm)	Water (µg/l)	Sediment (µg/kg)	Plankton (ppm)
Lake Ontario[1,2]	0.14 - 9.17	0.035 - 0.097	43 - 245	3.4 -11.8
Lake Erie[3,4]	0.2 - 7.8			
Lake Superior[5]	0.3 - 5.6			
Lake Huron[6]	0.16 - 11.0			
Lake Michigan[6,9]	0.1 - 165.3		3.72- 636	
Cayuga Lake[10]	3.4 - 9.7			
Lake St. Clair[16]	tr - 3.8	0.1 - 0.2		
Rivers				
Iowa				
Mississippi River[11]	0.9 - 5.5			
Texas				
Brazos River[12]		0.1 - 0.5		
Utah				
Green River[12]		0.1		
New York				
Hudson River[13]	7 - 350	1.0 -2,800	6.6 - 6,700,000	
Michigan				
Saginaw River[6,14]	6.9 - 165.3	0.1 - 0.21		
Kalamazoo River[7,15]		0.1 - 0.45	100 - 560	
Portage Creek[7]	0.01 - 164.56	0.1 - 0.48	10 - 475,400	
Wisconsin				
Milwaukee River[8]		.02 - 2.17		
Marine Environment				
Atlantic Ocean[17,18]	0.038- 0.190	0.0009- 0.0036		
Bay of Fundy[19]	0.07 - 1.54			
Gulf of Mexico/ Caribbean Sea[20,21]	0.032- 0.059			0.157- 1.055
Southern California[22]	0.04 - 6.6	0.0015- 0.019		

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TABLE 4
LAKE ONTARIO ECOSYSTEM[1]

FISH, µg/g			
Alewife	.14	-	4.36
Smelt	1.40	-	3.49
Slimy Sculpin	1.58	-	9.17
WATER ng/l	38	-	97
SEDIMENT, ng/g	43	-	245
NET PLANKTON, µg/g	3.4	-	11.8

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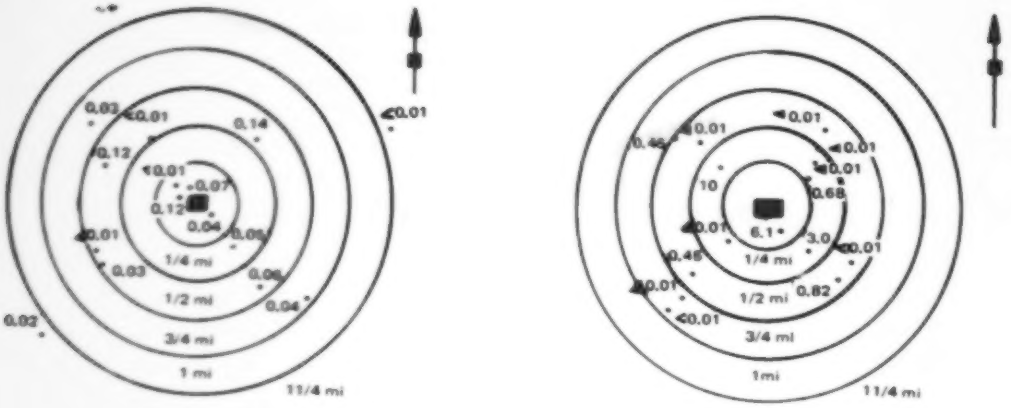
Figure 1

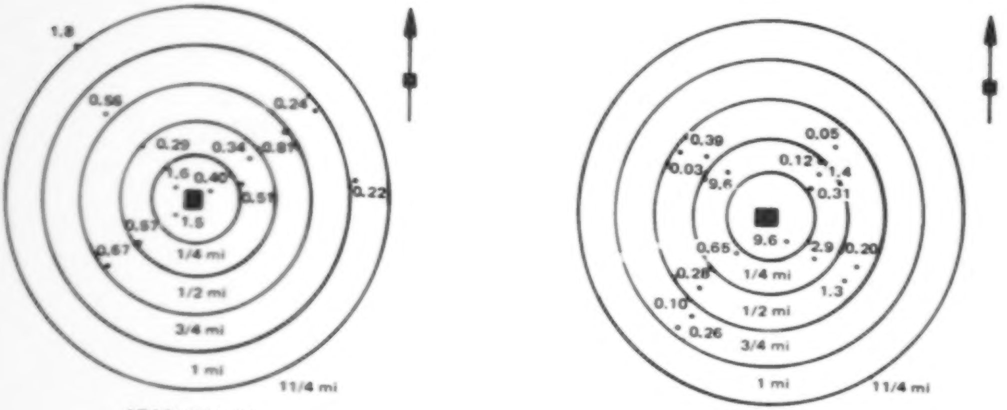
CONCENTRATION OF PCB'S IN SOIL WITH DISTANCE

(ppm)



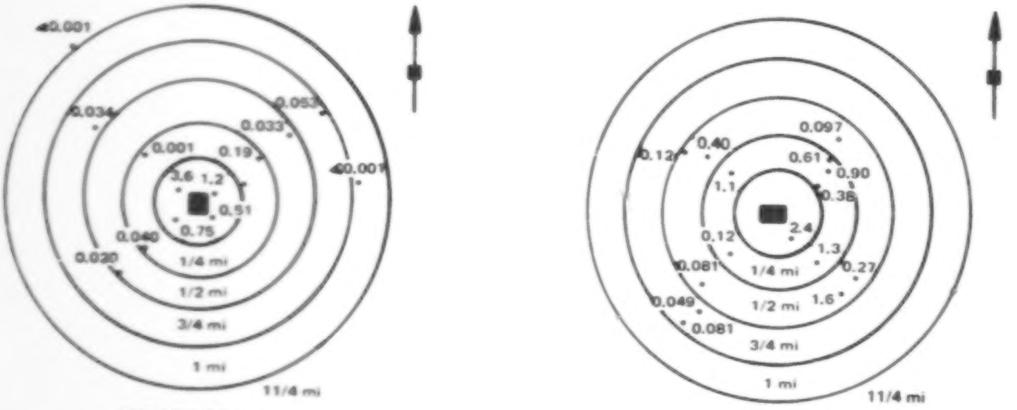
AROCLOR 1260
INVESTMENT CASTING COMPANY

AROCLOR 1242
PCB MANUFACTURER



AROCLOR 1260
INVESTMENT CASTING WAX MANUFACTURER

AROCLOR 1260
PCB MANUFACTURER



decachlorobipheny1
INVESTMENT CASTING WAX MANUFACTURER

decachlorobipheny1
PCB MANUFACTURER

MONITORING: THE TRIGGER FOR ACTION

Delivered by
I. Eugene Wallen, Ph. D.
Deputy Director, Office of Toxic Substances

to the
National Symposium on Environmental Monitoring
Las Vegas, Nevada -- September 15, 1975

Vinyl chloride air emissions . . . organics in drinking water . . . asbestos fibers in waste water effluents . . . polybrominated biphenyls in fish . . . these and many other toxic chemical concerns are being clarified by current monitoring efforts of the Office of Toxic Substances. In each of these instances, the speed and direction of the responses of Governmental regulatory machinery are critically dependent on monitoring data -- particularly recent data which can provide a reasonably sound basis for generalizations.

Two of the key informational concerns in addressing chemical problems are toxicity and exposure, and monitoring data provide the backbone of exposure estimates. While toxicity data may often be inadequate, acceptable monitoring data are rarely available at standard-setting time.

What are the problems inhibiting the ready availability of solid monitoring data? Why are the available data generally not well suited for standards setting? Why are we continually surprised by unanticipated chemical problems? Who has the resources? These questions go to the heart of this conference. Their answers inevitably involve a blurry mix of scientific, technical, organizational, and budgetary issues. Pernaps a brief review of a few recent case histories, together with examples of current efforts, will help to provide a perspective for the applications of monitoring data in the regulatory decision process.

EXAMPLES OF RECENT TOXIC SUBSTANCES MONITORING EFFORTS

Vinyl Chloride

Initial EPA monitoring activities were directed primarily to air emissions at PVC polymerization facilities. Upon discovery of the relationship of vinyl chloride to Angiosarcoma, monitoring patterns, sampling and analysis approaches and equipment, and data interpretation techniques were hastily developed by several EPA laboratories in early 1974. A preliminary sampling effort at one facility provided much needed experience in refining the approaches to be used in more refined efforts at seven other industrial complexes. The entire sampling and analysis program was carried out in less than three months, and there is no doubt that the results had a major impact on the EPA decision to set an air standard for vinyl chloride. Details of the approach and the results are set forth in the report *Preliminary Assessment of the Environmental Problems Associated with Vinyl Chloride and Polyvinyl Chloride*, Environmental Protection Agency, September 1974. In retrospect, this *ad hoc* monitoring effort was probably about as good as could have been expected given the time and resource constraints and the lack of previous experience with vinyl chloride. One major shortcoming was the failure to convene a meeting of all the sampling and analysis teams early in the program to identify problem areas and promote greater uniformity in the approaches that were used.

The recent discovery of vinyl chloride in drinking water and near waste disposal sites has caused a reexamination of the initial conclusions that these were not areas of serious concern. Initial monitoring data, coupled with tests of the behavior of vinyl chloride in water, suggested that there was little likelihood that vinyl chloride would reach drinking water supplies as the result of vinyl chloride effluent discharges. With regard to landfills, it was assumed that wastes from PVC plants and discarded PVC products would probably not be problems. Monitoring of selected sites hopefully would clarify the need for regulatory actions other than current steps directed to air emissions.

A third type of concern is related to the possible migration of vinyl chloride out of finished PVC products into the environment; thus possibly establishing a background level of the vinyl chloride monomer in air. While skeptics have doubted this possibility, there are several unconfirmed and unexplained reports of detection of vinyl chloride distant from either vinyl chloride or PVC plants. Sampling for vinyl chloride is planned at a number of potential sites where monomer migration might have taken place.

Organics in Drinking Water

The report *Preliminary Assessment of Suspected Carcinogens in Drinking Water*, Environmental Protection Agency, June 1975, detailed the initial results of an EPA monitoring survey of organics in drinking water. Eighty water supplies were chosen and six specific organics of potential concern . . . the four trihalomethanes (chloroform, bromodichloromethane, dibromochloromethane, and bromoform), carbon tetrachloride, and 1,2 dichloroethane . . . were found. These 80 supplies provided a reasonably representative sample of community drinking water supplies that chlorinate their water, and represented a wide variety of raw water sources, treatment techniques, and geographical locations. Based on the survey findings, it appeared that chlorination may have contributed to the formation of the four trihalomethanes.

For a more comprehensive survey of the organic content of finished water, a second portion of the Survey investigated 10 of the 80 cities with sites representing 5 major categories of raw water sources. Preliminary analyses of the drinking water of the first five cities have identified over 85 organics. The water supplies of the five remaining cities were surveyed more recently, and the results are expected to be reported by the end of the year.

The results of this monitoring effort are having a major impact on the regulatory and research efforts of EPA. Indeed, it has probably been the most important single activity in shaping future Agency actions concerning organics in drinking water.

Environmental Levels of Asbestos

A nation-wide asbestos sampling program is underway to determine the environmental levels of asbestos resulting from discharges from various sources. Thirty-two sampling locations have been chosen to include four major categories of asbestos dischargers. A natural site category was selected because of asbestos rock formations which may contribute significant amounts of asbestos in runoff or emissions as a result of natural weathering processes. Other site categories are asbestos mining; mining of other ores (such as talc and vermiculite which may also be sources of asbestos); and asbestos manufacturing. For all categories, both air and water samples are being taken. Over 60 sampling sites have been chosen, including water supplies of several major cities, such as San Francisco, Denver, Chicago, Atlanta, and Dallas. The sampling has begun and a report detailing the analyses should be available by mid-1976.

Previously Unidentified Pollutants in Water

As a part of the early warning efforts of the Office of Toxic Substances, 200 water samples from sites in industrial areas throughout the country are being collected and analyzed. It is anticipated that collections will be made at about 100 sites in 30 to 40 industrial areas. Each sample will be subjected to three subsample analyses to screen for (1) inorganics, (2) volatile organics, and (3) non-volatile organics. The purpose of this monitoring program is to identify specific chemicals in surface waters having an industrial effluent origin, and then to clarify which should be of concern in view of their potential to reach man through drinking water, fish products, or recreational exposure. The monitoring information, together with data on the toxicity of the identified chemicals, should provide a basis for initial judgments on the possible need for regulatory actions.

Multimedia Exposure to Halogenated Organics

A fifth program involves monitoring studies to determine the levels of selected halogenated organics in air, water, soil, and food in four limited geographic areas, and parallel investigations to determine the levels of the same chemicals in the blood, tissue, and urine of human populations in these areas. A review will be undertaken of the causes of death in these areas in comparison with death rates in other areas, as well as with national averages. The sources of environmental discharges of the chemicals also will be identified.

This project is intended to utilize monitoring, epidemiological, statistical, and other analytical techniques in clarifying the degree to which different types of pollutant sources may contribute to human health problems.

THE USE OF MONITORING DATA IN SETTING STANDARDS

An estimate of likely exposure should, of course, be central in deciding the need for, character of, and impact resulting from a proposed regulatory action to curtail the discharge of a chemical into the environment. Current environmental levels, fluctuations, and trends are of interest in assessing the benefits to the environment of curtailing exposure, as well as in detailing the costs involved in achieving reduced exposure levels. In grappling with the costs of regulation, -- for example, in setting maximum contaminant levels in drinking water, allowable chemical concentrations in water effluents, or pesticides tolerances -- the severity and urgency of the problem and the numbers of activities which would be affected by different types of compliance are all critically dependent on monitoring data. More often than not, the available data are so inconclusive that these questions are only answered in a very cursory way. However, as economic concerns over regulatory actions heighten, the insistences by the Congress and the courts as well as by the Executive branch of the Government that hard evidence back up those actions increase.

REVIEW AND EVALUATION OF EXISTING MONITORING DATA

Sources of monitoring information generally were prepared for purposes other than regulation of specific chemicals. When these data are compiled as a part of the consideration of proposed regulation, they must be reassembled and reformattedso as to contribute to calculations of the exposure of man and the environment to a particular substance. Some of the considerations used in such calculations must include the relative importance of the alternative pathways from the environment to man or other affected organism; the geographic sites of exposure; the internal variability of the affected populations; the effects of acute or chronic rates of exposure; the persistence of the chemical; the toxicity of its breakdown products; and other similar characteristics. Although monitoring data may be used to gain significant insight into several of these considerations, they generally must be selected according to application.

Monitoring information to be gathered will include concentrations and recent trends in air, surface and drinking water, groundwater, soil, food, sediment, aquatic and terrestrial organisms, and human tissues and body fluids. Details will also be needed on the methods of collecting the samples, interferences, meteorological data, and analytical methods employed.

Already existing monitoring data will come from computerized searches, specialized data centers, university programs, federal programs, state programs, and science information exchanges.

These data must be keyed to the specific types of limitations necessary to reduce discharges into the environment, thus reducing the risks of environmental exposure. Data will be collected on a highly selective basis, with no necessity of obtaining comprehensive monitoring data for all sources and all media.

DATA GAPS

It will be necessary to identify data gaps and develop an appropriate environmental sampling plan designed to yield the data required. Major air, water, soil, sediment, and biota monitoring programs may have to be undertaken. In identifying suitable sampling sites, pertinent meteorological, hydrogeological, and demographic considerations, along with identification and evaluation of the various sources of discharge, must be considered. Acceptable criteria must be developed with a defensible rationale for selecting the sites and the types of sampling to be undertaken. It often may be desirable to establish seasonal trends of toxic substances levels at various locations and the concentration levels in different media. In some cases cross-media transport mechanisms must be considered.

SAMPLING EQUIPMENT

A wide spectrum of sampling equipment must be available and used to collect and preserve the integrity of the samples. Concentrations of the sample may be required in the field for some toxic chemicals. The analytic laboratory must be sufficiently equipped to perform quantitative trace chemical analyses in various media. Readily available instrumentation should include atomic absorption spectrophotometer, spark source mass spectrograph, high and low resolution mass spectrometers, gas chromatograph/mass spectrometer, UV-visible spectrometer, gas chromatograph, and associated items.

DATA PACKAGE

The data must be fitted into integrated packages that will profile human and environmental exposure to these chemicals in the media of concern, and assess the degree of harmful exposure of animals, plants, and microorganisms from the production, use, and disposal of these chemicals. The profile must be keyed to the available approaches for reducing environmental levels by controlling sources.

Relevant data are required on the levels of the chemical which are identified in air, drinking and surface water, groundwater, dust, sediment, soil, and other media. Reported sources of contamination should be indicated and, for those substances that occur naturally, background levels should be identified. Maps should be provided showing the distribution of sampling areas and levels identified wherever possible.

Data also are needed concerning (1) behavior of the chemicals in the environment; (2) occurrence of the chemical in food and other products that come in contact with man; (3) exposure and biological accumulation; and (4) environmental trends.

In conclusion, although monitoring data may be collected for research, demonstration, management, or other purposes, properly massaged data are useful to the regulator in a variety of contexts and they may trigger or obviate several types of regulatory considerations.

CHEMICALS AND THE ENVIRONMENT

Delivered by
Glenn E. Schweitzer
Director, Office of Toxic Substances

to the
American Dye Manufacturers Institute, Inc.
Absecon, New Jersey -- September 11, 1975

Two weeks ago, the lead article in Sports Illustrated highlighted a series of unfortunate incidents affecting fishing activities which have resulted from environmental contamination by polychlorinated biphenyls. For many of you, this magazine may simply be a vehicle for passing time in an airplane. For others, and for myself, Sports Illustrated reflects many of those activities that make life truly enjoyable. While we are accustomed to encountering problems resulting from industrial chemicals in our newspapers, in popular magazines, and in the trade press, now even the last recluse for sports lovers has been invaded.

It may seem that polychlorinated biphenyls are a long way from dyes. However, the types of concerns surrounding this chemical and many other commercial chemicals as well will continue to trigger actions by regulatory agencies and public interest groups, and indeed by industry itself, which can have significant implications for your industry.

Today, I would like to report to you on recent developments in several areas which have stimulated a considerable amount of discussion within and outside Government during recent months. A number of issues are being brought to a head in large measure by specific actions on the part of Congress and the regulatory agencies. Indeed, specific actions are often required to bring into sharp focus important policy issues which had previously been considered largely in the context of academic discussions.

More specifically, I would like to make a few observations on the environmental decision-making process, approaches to the control of carcinogens, and the likely impact of the Toxic Substances Control Act on industry. These areas are obviously interrelated. Also, while I will try to confine my remarks to industrial chemicals, clearly there are many overlaps in the approaches to the control of industrial chemicals and chemicals used for other purposes such as consumer products, food additives, drugs, and pesticides. At the outset, let me emphasize that my comments will be oriented toward raising issues and questions rather than prescribing solutions. This seems appropriate since in most cases general prescriptions either must be so broad as to be almost meaningless or, if specific, they frequently ignore the complexities of the real world of chemicals.

The Environmental Decision-Making Process

Obviously, a key concern in any decision-making process is, "Who decides?" In the environmental area, the answer to this question varies with the particular type of decision. Within Government, the decision maker can range all the way from an appellate court to a relatively junior Government official. Outside Government, a Board of Directors may decide or, at the other extreme, an individual customer may determine the fate of a chemical.

A key related concern is how and when issues are escalated up the decision-making ladder. Within Government, the escalation process depends both on internal procedures and on the extent to which an adversely affected party decides to press the issue. The squeaky wheel does command attention.

Related to the participants in the decision-making process is the structure of the process itself. While the larger companies and the better financed public interest groups can keep abreast of the procedural steps leading up to a decision, we are increasingly concerned over the difficulties facing smaller organizations which all too often learn about an important decision only after the fact. Many trade associations are providing a useful service to the smaller companies in this regard, although it seems only realistic to recognize that smaller companies will continue to have greater difficulties in staying abreast of and influencing the decision-making process.

Certainly in the case of EPA, many individuals and groups within and outside the Agency are involved in influencing any major decision that eventually emerges. The internal and external review mechanisms, the comment and hearing procedures, and the opportunities for informal inputs may not seem adequate to an outsider. However, from the point of view of a regulatory official, there would seem to be many opportunities for all interested parties to provide inputs into the decision-making process. This, of course, does not mean that the decision would necessarily reflect any particular input, since there is bound to be controversy in any decision which has major environmental impact and attendant economic effects.

At the same time, I am not implying that the decision-making process cannot be improved. For example, the National Academy of Sciences has raised the question as to whether a Commission for making regulatory decisions affecting the environment would be preferable to a single EPA Administrator. The Academy has also urged more extensive external reviews of pending EPA decisions, although in almost the same breath has urged that the time involved in the decision-making process be shortened.

Another important aspect of environmental decision making relates to the burden of proof. This aspect has been underscored in recently introduced legislation which would seem to shift a greater burden to those parties that derive commercial benefits from the chemicals in question. However, these legislative proposals are limited to the burden of proof in a judicial proceeding and thus are only indirectly related to requirements for considering regulatory actions during the development and promulgation of regulations and during adjudicatory hearings. With regard to industrial chemicals in general, and the Toxic Substances Control Act in particular, the initial burden of establishing the need for regulatory actions would remain with the regulatory agencies.

Industry is understandably concerned that an extreme interpretation of burden of proof requirements might call for industry to prove a negative -- that is, that there is no hazard or risk associated with the use of chemical -- a task which some argue is impossible. At the same time, it seems clear that the proponents of the use of chemicals which are deliberately given to people or deliberately introduced into the environment should demonstrate the efficacy and safety of these chemicals. This principle is set forth in our laws governing the development and use of food additivies, drugs, and pesticides. With regard to industrial chemicals, including those chemicals which are not intended for widespread distribution in the environment, industry also has a responsibility to insure the safety of their employees, the residents surrounding manufacturing facilities, and other people and environmental resources that may come into contact with the chemicals. Of course, the criteria to be used in assessing the hazards associated with chemicals clearly must take into account the intended uses, the likelihood of unintended uses, and the attendant possibilities of environmental release.

Another aspect of decision making relates to the weight to be given to the costs, the risks, and the benefits associated with the concerned chemical or chemicals. For some time EPA has been committed to a careful consideration of all of these factors in addressing industrial chemicals. However, translating a very general, albeit very sincere, commitment into practical decision making is not always easy. Formulas do not exist for trading off health and ecological considerations against economic and societal benefits. Nevertheless, I believe that all will agree that in every case all relevant considerations should be clearly arrayed for the decision maker, considerations which incorporate the best available data and which identify the unknown factors as well as the known factors. The basis for the decision should then be fully explained to the public.

The Control of Carcinogens

The evidence linking some industrial chemicals with increased cancer incidence continues to mount. The recent set of "cancer maps" prepared by the National Cancer Institute shows very conspicuous high levels of incidence of certain types of cancer in many areas characterized by heavy concentrations of the chemical industry. The bioassay program of that same institution is uncovering more and more important chemicals which produce tumors in experimental animals. Other toxicological investigations and epidemiological studies are also highlighting previously unsuspected cancer risks associated with exposure to certain chemical.

At the same time that additional chemicals are being implicated as possibly being the causative agents for induction of cancer, our monitoring programs are detecting levels of many of these chemicals in different environmental media. Perhaps the discoveries of greatest concern are resulting from our monitoring programs directed to drinking water supplies. In any event, new data on toxicity and likely exposure levels are constantly adding concerns over the risks associated with the manufacture, use, distribution, and disposal of chemicals in general, and of carcinogens in particular.

But how can the risks associated with carcinogens be assessed? Three approaches have usually been tried. The first approach is simply to decree that any risk is unacceptable -- a concept repeatedly rejected by EPA. Another approach is to attempt to extrapolate from the rate of tumor incidence in one or more animal experiments and using various statistical techniques to derive a risk factor (e.g. less that 1 to 1,000,000; less than 1 to 1/100,000) at the level of exposure likely to be encountered in the environment. This risk factor is then multiplied by the number of people who are likely to be exposed to the chemical to provide an estimate of the risk to the overall population. This approach, while appealing to many, and particularly those interested in quantifying risk/benefit tradeoffs, is inevitably plagued by uncertainties in both the animal test data and the exposed population estimates. A third, and in my view a preferred approach, involves less precision, but hopefully more realism in deriving estimates. All available data on health effects are arrayed, including the carrying out of statistical extrapolations when possible to provide very general estimates of the levels of risks to an individual. Consideration is also given to the monitoring and related data concerning exposure levels. No attempt is made to derive a single risk number, but all data are examined in reaching a conclusion as to a "ballpark" level of risk. If a single number is required, the best estimate is then bracketed with estimates of the uncertainties and a qualitative description of the uncertainties.

There is no reason not to balance the costs, risks, and benefits associated with carcinogens in much the same way that these factors are balanced in decisions involving other chemicals. In my view, the only methodological differences in assessing the need for controlling carcinogens as contrasted to non-carcinogens -- assuming such a distinction can be made -- relate to the techniques for assessing risks. Of course, as a practical matter, we cannot neglect the fact that a major element in addressing carcinogens will inevitably be the emotional aspect of dealing with the risk of cancer which has affected the lives of so many people. At the same time, it is far from clear that cancer should be our principal health concern in assessing chemical hazard.

Toxic Substances Legislation

As you know, currently both Houses of the Congress are actively working on the Toxic Substances Control Act -- a much needed piece of legislation that has been pending for more than four years. While there are significant differences between the several versions of the legislation, all versions provide for annual reporting of chemical production activities, testing by industry of selected chemicals, industrial notification of the Government of the identity of new chemicals prior to their introduction into commerce, and authority to limit production or use when there is an unreasonable risk that cannot be adequately addressed under other existing authorities.

A major thrust of this legislation is to examine the health and ecological effects of new commercial chemicals before major investments have been made for their production. This "front-end" approach -- designed to cut off problems at the pass -- will not only address potential problems before the damage is done, but will also minimize the economic dislocations attendant to corrective actions.

With regard to the impact of the legislation on industry, the reports prepared by industry -- and particularly Dow and Snell -- have in our view distorted some of the impacts that are likely to result. Therefore, I would urge caution in citing these reports as an authoritative estimate of what is likely to happen when the legislation is enacted.

Clearly, the final shape of the legislation and the character of the implementing regulations will affect the impact. Perhaps it would be useful to underscore several aspects of the legislation which we consider particularly important in this regard.

-- Any requirements to publish a list of chemicals as a preliminary step to establishing requirements for premarket screening or for testing are unadvisable. If there is sufficient evidence to suspect a chemical or chemical class, the appropriate requirement should be established forthwith. There is no need for a list which will simply delay and confuse the process and raise premature concerns about the eventual regulatory fate of a number of chemicals.

-- There should be a provision to exclude research chemicals product in very small amounts from pre-market reporting requirements when appropriate.

-- Comprehensive annual reporting of all commercial chemicals is not of sufficiently high priority to warrant the expense that would be incurred by industry and Government to carry out such a requirement in a responsible fashion. Rather, selected reporting of those chemicals of possible concern makes far more sense.

-- Similarly, we do not consider mandatory submission of all health and safety studies conducted by industry during the past 40 years desirable. Rather, authority to request such studies as needed would be far preferable.

-- EPA has no intention to require extensive premarket testing on all new chemicals. On the one hand, we cannot predict what chemicals will be developed, and as a practical matter it is not possible to develop test requirements that make sense for all possible chemicals and all possible uses. Of equal importance is our conviction that concentrating the limited available resources on a few classes of chemicals which are known to be troublesome will pay far higher environmental dividends than a broad shotgun approach.

Common Goals

The objectives of the programs of my Office are quite straight forward, namely, to reduce the probability of chemical incidents harmful to man or the environment through

-- safer products,
-- cleaner and safer manufacturing processes, and
-- better product handling and disposal

without necessarily

-- increasing product costs,
-- blunting R&D activities,
-- distorting configuration of the industry, or
-- jeopardizing the U.S. competitive position.

Obviously, these goals are not unique to us or to the Government in general, nor are they particularly controversial. Nevertheless, I feel that it is important to make such goals explicit.

From my vantage point, there are two routes for reaching these goals. Industrial actions can be forced by regulations, or industrial actions can be undertaken on a voluntary basis. Clearly, there will be a mix of these approaches. I would hope that we could rely increasingly on voluntary steps by industry, which are usually less painful for all concerned, but actions in this regard rest with you.

HEARINGS ON PCBs

Delivered by
Glenn E. Schweitzer
Director, Office of Toxic Substances

to the
Wisconsin Department of Natural Resources
Madison, WI -- August 29, 1975

I greatly appreciate the opportunity to present the views of the Environmental Protection Agency concerning the environmental problems associated with the manufacture, use, distribution, and disposal of polychlorinated biphenyls (PCBs). Since its initial days the Agency has been concerned with practical steps that could be taken to clarify and reduce the environmental risks attendant to commercial applications of PCBs. More recently the Agency has intensified its efforts to help insure that unnecessary hazards are effectively curtailed. Thus, we fully share your concerns, and we will continue to work with the State Governments and other interested organizations in seeking feasible solutions to this problem.

In view of the background papers that are available and the detailed statements being presented by specialists participating in these hearings, I will limit my comments to a brief summary of the history of the PCB problem, recent developments that have heightened interest in PCBs, and the current spread of EPA activities directed to PCBs. I will then comment on several aspects of particular interest to the State of Wisconsin.

1972 Findings of Interdepartmental Task Force and Ensuing Actions

In May 1972, the Interdepartmental Task Force concluded that PCBs were highly persistent, could be found in all parts of the environment, could bioaccumulate in fish by a factor of up to 75,000, and could have serious adverse effects on human health. The Task Force urged discontinuance of all uses of PCBs except uses in closed electrical systems and called for enactment of the Toxic Substances Control Act to provide a needed regulatory mechanism to deal with PCBs and other problems of this type.

Largely as a result of the activities of the Task Force, the Monsanto Company, the sole US producer of PCBs at that time, voluntarily limited its sales to manufacturers of closed electrical systems. Also, EPA promptly announced that it would begin restricting the discharges of industrial effluents so that the levels of PCBs in rivers or lakes do not exceed 10 ppt. FDA took steps to establish PCB tolerances for several types of food (from .2 ppm in baby food to 5 ppm in fish) and to limit PCB contamination in food packaging and food plants.

As a further follow-up to the Task Force recommendations, the

General Services Administration amended its procurement specifications to ban PCBs in off-shore oil operations. The American National Standards Institute issued guidelines for industry on the use, disposal, and labelling of PCBs.

Internationally, a Decision of the Organization for Economic Cooperation and Development (OECD) 1973 provides that PCBs shall not be used for industrial or commercial purposes except in certain closed systems. However, even with respect to the excepted uses, the OECD Council (a) decided that PCBs should only be used when adequate environmental controls are exercised and when benefits outweigh the risks, and (b) recommended that countries work toward the elimination of PCBs in small capacitors. The Decision leaves it to Member countries to go beyond the Council agreements and, in effect, invites governments to phase out PCB uses wherever possible. Japan, in the wake of PCB contamination of rice oil that adversely affected 1000 people, banned future production or import of PCBs. More recently the government of Canada has begun to collect necessary data for restricting PCBs pursuant to a new Environmental Contaminants Act which should be enacted this year.

Developments Since the Task Force Report

Health and Ecological Effects

Recent research results have heightened concern over the toxicity of PCBs previously documented in the Report of the Interdepartmental Task Force. Concentrations as low as 2.5 and 5 ppm have produced serious adverse health effects in monkeys, including loss of hair, acneform lesions, loss of weight, increased secretion of total urinary ketosteroids, irregularities in menstrual cycles, impaired ability to maintain pregnancy, and undersized offspring. A still unpublished report indicates malignant liver tumors in rats exposed to one grade of PCB at levels of 100 ppm. Several superficial reports of chloracne among workers exposed to PCBs have been received. Also, concentrations of 5 ppm in fish eggs have resulted in fry mortality.

In considering these effects it is important to remember that there are eight commercial grades of PCBs, and their toxicity characteristics may vary to some degree. However, there is no basis for assuming that any one of the grades is not a potential hazard.

Monitoring and Exposure Data

As a result of the FDA actions described above, the PCB levels in foods have been steadily declining. At the same time, however, the levels detected in fish and wildlife appear to have increased. Available monitoring data for PCBs in the ambient air, water, sediment, soil, or human tissues do not provide a good basis for estimating national environmental trends. For example, analyses of water samples have seldom extended into the parts per trillion range, and thus only rarely have PCBs been detected. Limited adipose tissue samples for FY 1972 and 1973 indicate a slight downward trend with levels in excess of 3 ppm being observed. Unusually high levels of PCBs have been detected in recent months in the fish in Lake Michigan (up to 165 ppm), Lake Pepin (up to 40 ppm), the Hudson River (up to 350 ppm), and Southern California (up to 6.6 ppm), although the average levels are significantly lower than these upper limits. PCBs have been detected in sludge from sewage treatment plants as well as in the effluents from these plants. PCBs have been identified in only two drinking water supplies during the past year. There have been five water spills involving PCB leakage from transformers during the past year, and currently there are tens of thousands of capacitors, each containing several gallons of PCBs, awaiting disposal.

Production, Imports, and Uses

While Monsanto is believed to be limiting its sales to manufacturers of closed electrical systems, information has been received by EPA indicating that PCB reprocessors may be selling PCBs for other uses. It is believed that most of the PCB imports (which exceeded 375,000 pounds in 1974) are not used in closed electrical systems. Among the PCB uses which are known to persist in the US at present are applications in investment casting processes, heat exchange fluids, and hydraulic fluids. There are a variety of other potential uses of PCBs although firm evidence of such current uses is not in hand.

With regard to substitutes, Dow Chemical has developed a product for use in large power capacitors, and Dow Corning has a prodwhich can substitute for PCBs in certain transformer applications. At least one of these substitutes is reportedly being introduced at the present time in Japan.

Recent Regulatory Actions

In 1973, Water Quality Criteria were proposed to limit PCBs to 2 ppt in ambient waters. Also, a national effluent standard for PCBs was proposed under Section 307(a) of FWPCA. PCBs were included in the advanced proposal of a hazardous substances list under Section 311 of the FWPCA in 1974. Finally, NPDES permits that limit the discharge of PCBs have been issued for at least six facilities; preliminary reports indicate that approximately 10-15 other discharge permits may contain effluent limitations for PCBs. In addition, the effluent guidelines promulgated for the steam electric power generating category contain limitations requiring no discharge of PCBs. A significant percentage of the permits issued for this category to date contain these limitations.

As you know, several states are currently considering imposing limitations on PCBs.

Ongoing Activities of EPA

The following EPA activities to assess and control the PCB problem have been underway for some time.

1. A water quality criteria level of 1 ppt will soon undergo interagency review prior to final promulgation. The originally proposed level of 2 ppt has been reduced in view of the recent ecological effects data.

2. Detailed documentation necessary to support a national standard for water effluent discharges under Section 307(a) is being assembled with issuance of a revised proposed standard scheduled in the near future.

3. Proposed levels of harmful quantities of PCBs accidentally released into navigable waters and rates of penalties for such spills are currently being developed pursuant to Section 311 of the FWPCA.

4. A laboratory demonstration program is underway to develop and test control technology for treatment of PCB manufacturing wastes, including the aqueous effluent from PCB users and the discharge from leaks from transformers and capacitors.

5. The scientific literature concerning the health and ecological effects of PCBs is being reviewed. Further, a continuing research program is investigating the metabolism and effects of PCBs. As part of this program, several studies have examined the effects of PCBs in rats after long-term feeding regimes, especially effects on reproduction, liver function, carcinogenesis, and hemoglobin metabolism.

6. Collection and analysis of adipose tissues are continuing.

7. Several laboratories have been conducting research on the ecological effects and environmental fate of PCBs.

8. Studies of the behavior of PCBs in soil, with particular attention to possible ground water contamination following a spill, are underway.

9. Analyses of the technological and cost aspects of using substitutes for PCBs in closed electrical systems are underway.

10. Technical assistance is routinely provided on the storage and disposal of PCB-containing wastes. In addition test burns of capacitors containing such wastes in a high temperature incinerator are planned for early 1976.

Newly Initiated Activities of EPA

In view of the new evidence concerning the toxicity of PCBs and the recent reports of high environmental levels in several areas of the country, EPA has accelerated its efforts directed to PCBs. These activities, being carried out in cooperations with other Federal and State agencies, include:

1. The National Academy of Sciences is being requested to give special attention to whether a drinking water standard for PCBs is needed. Meanwhile, monitoring for PCBs in drinking water supplies is being expanded.

2. Information concerning the best sampling and analysis techniques for PCBs in different media is being assembled and reviewed to provide guidance to the Regions, states, contractors, and other organizations involved in monitoring.

3. A limited number of ambient air, water, sediment, soil, and fish samples are being collected and analyzed from throughout the country. These data, together with existing data, will provide an up-to-date overview of the current level of environmental contamination by PCBs.

4. In response to local concerns, several Regions will be measuring PCB levels in effluent streams from industrial and municipal sources, receiving waters, and associated fish populations to assist in relating specific discharges to environmental levels of particular concern.

5. Information concerning the use and distribution of PCBs and the levels of PCBs in effluent discharges has been requested from 84 companies which are believed to handle PCB compounds or mixtures in their operations. These requests for information have been made pursuant to EPA's authority under Section 308 of FWPCA and Section 114 of the Clean Air Act.

6. A special review of past and recent data to assess the carcinogenic potential of PCBs is underway.

7. Test data on the chemical properties and potential bioactivity of substitutes for PCBs have been requested from Dow Chemical and Dow Corning.

8. Imported PCBs and polychlorinated terphenyls (PCTs), are being analyzed to identify possible contaminants. In additon, the techniques for detecting PCBs, PCTs, and polybrominated biphenyls (PBBs) are being examined to determine whether interference among the substances prevents reliable analysis for any one of them.

9. General guidance for proper disposal of wastes containing PCBs will be developed.

10. The Department of Defense, the General Services Administration, and other agencies will be requested to review and to amend as appropriate their procurement specifications and those of their contractors concerning the purchase of PCBs and materials containing PCBs.

11. Consultations with the Japanese Government are being initiated concerning their experience in implementing a ban on the production and import of PCBs.

12. Consultations with OECD Governments are continuing in an effort to determine the effectiveness of the 1973 Decision in reducing the PCB problem on a worldwide basis and to encourage expeditious carrying out of the provisions of the 1973 agreement.

13. Consultations are being conducted with the Canadian Government to inform them of our information and activities concerning PCB users in Canada and to coordinate future actions.

Reducing Contamination Levels in the Aquatic Environment

EPA considers that a PCB concentration of 1 ppt in the ambient water environment represents an appropriate goal for the nation. This conclusion is reflected in the Water Quality Criteria which are currently undergoing final review prior to promulgation. We would suggest that this goal serve as very broad guidance in developing strategies on a nationwide basis and locally to control discharges of PCBs into our waterways.

However, we are not prepared at this time to provide more specific guidance on the control strategies that should be adopted nationally or locally concerning the regulation of individual dischargers. We are developing a nationwide strategy with a significant component of our approach to be reflected in a toxic effluent standard for PCBs scheduled for proposal early next year. At the same time, we recognize that a nationwide standard might not be adequate in addressing local problems in some areas, and the control strategies adopted locally may of necessity require an elaboration of the national approach.

In any event, we believe that better information is needed concerning the specific facilities discharging into the aquatic environment before reaching a final judgement on a national standard. Also, it is important to clarify the portion of the PCB contamination problem which can be attributed to specific dischargers and the practical feasibility of reducing the discharges. As a key step in this regard, on August 16, we requested from 84 companies detailed information concerning their activities involving PCBs including details on their uses of PCBs and monitoring data in the effluent stream and in the receiving waters. With this information in hand, we believe we will be in a much better position to develop meaningful regulatory approaches which take into account the realities of current industrial activities.

The Role of the Toxic Substances Control Act

As I have indicated, EPA is currently utilizing or preparing to utilize authorities under the Federal Water Pollution Control Act which address the problems of effluents and spills containing PCBs in an effort to reduce the environmental levels of PCBs. Additional authorities may also be used if warranted by further information concerning levels of PCBs in drinking water or even possibly in air. However, each of these available authorities has a limited focus and none provides the most critically needed authority -- to limit selected uses and distribution of PCBs. Indeed, even with the cooperation of Monsanto to limit production as well as the use of existing authorities, it seems clear that the PCB problem will continue to persist in some form.

Under the pending Toxic Substances Control Act, however, EPA would have the needed authority and could deal with the problem in a far more effective manner. In addition to authority to restrict the production and use of PCBs, the legislation would, if necessary, enable EPA to require testing concerning the health and ecological effects of the proposed substitutes for PCBs.

With regard to the limitations that might be considered under this legislation, the 1972 Task Force Report concluded that there were appropriate substitutes, presumably at reasonable cost, for all non-electrical uses of PCB. We have no information which would contradict this conclusion. However, we currently are carefully analyzing each PCB use and the technological, environmental, and cost aspects of possible substitutes to insure the soundness of the conclusion. Also, we are carefully reviewing the recent developments concerning substitutes for PCBs in closed electrical systems before reaching our final conclusions concerning the extent and character of limitations that would be appropriate under this authority. We are optimistic that we will have this authority within a few months, but as you know, further movement in this regard rests with Congress.

Finally, one key aspect of the Toxic Substances Control Act should be emphasized: the authority to review new chemicals before they are marketed and if appropriate require testing or take steps to limit the production or use if there is reason to believe a hazard to human health or the environment might ensue. This preventive or "front-end" approach to the control of chemical hazards would provide a more reasonable and cost-effective approach than current efforts to correct problems after the damage has been done. Not only would the public benefit from the environmental point of view but also the economic costs to industry would be minimized by taking actions prior to the time major investments would be made. It is clear that the past policies of allowing uncontrolled proliferation of chemicals such as PCBs in the environment, chemicals which have proven to be both persistent as well as hazardous, can no longer be tolerated.

Experience in Japan

The most relevant foreign experience in regulating PCBs has probably been the recent efforts in Japan where PCBs have been under governmental regulation since 1972. The Japanese Government has recently provided us with some preliminary insights as to their experience. The following comments are based on the initial reports we have received, and we plan to obtain more definitive information in the near future.

According to information provided by the Japanese Government, there has been practically no production, import, or export of PCBs in Japan since 1972. The only two companies which had been producing PCBs in Japan stopped production and suspended sales in early 1972. One exception has been the production of PCBs for railroad transformers which was discontinued in September 1973. Use of existing stocks of railroad transformers and condensers, but no new equipment, using PCBs is permitted. Even this limited use is subject to the restriction that no discharge of PCBs to the environment may occur. Beginning in 1976, paper plants will be prohibited from accepting PCB contaminated paper for recycling and such plants will be required to build treatment plants which will meet general discharge standards.

Further, we understand that the import of equipment using PCBs has also been virtually eliminated as of September 1972, and for those few products which are permitted into the country, importers must cooperate with the ultimate users to ensure that the components containing PCBs are recovered and properly disposed. Disposal is regulated by the Waste Disposal and Public Cleaning Control Law which was amended in February 1975 to include PCBs. Currently there are no regulations for labelling or handling PCBs.

The present limitations on the use, import, and export of PCB are based on Article 3 of the Chemical Substances Control Law which went into effect on June 10, 1974. Any manufacturer who wishes to produce PCBs in the future must apply to the Ministry of International Trade and Industry, although approval of such a request is regarded as highly unlikely. The Japanese Government projects that a total ban on PCBs will take effect in approximately six to ten years, when the current stock of equipment containing PCBs is exhausted.

The Japanese Government has established PCB contamination limits for fish and shellfish of 3 ppm for near-shore varieties and 0.5 ppm for ocean varieties. These limits are derived from a basic limitation for human intake of 5 mg/kg of body weight per day. Guidelines first set in 1973 for water quality and bottom sediment were revised in February 1975 to "not detectable" (less than 0.5 ppb) for ambient water and 10 ppm for bottom sediment. These standards are not necessarily permanent standards, since they were set with current monitoring capabilities in mind. Under the Water Quality Control Law, the authority used in setting these standards, penalties are imposed for exceeding authorized limits. Monitoring of the water quality and bottom sediment by each prefecture is required by this Law.

We have only very sketchy information concerning effluent limitations. According to the reports we have received, the Japanese Prime Minister's Office Ordinance based on Article 3 of the Water Control Law sets the maximum permissible PCB concentration in effluents at the point of discharge into rivers or lakes at 3 ppm. Coupled with this limitation is a provision authorizing a penalty for exceeding the effluent limit.

The environmental levels of PCBs in Japan have subsided in the last two years and are expected to continue to diminish. In a 1974 survey of bottom sediment including 1789 samples, 14 samples had PCB concentrations of over 50 ppm, 37 had concentrations of 10 to 50 ppm, and 21 had concentrations of 5 to 10 ppm. In the previous year, some PCB levels had exceeded 10,000 ppm; no such peaks were found in 1974. Concentrations of PCBs in the milk of mothers were down over the previous two years, although 25 percent of the samples were contaminated in excess of the prescribed level.

The Japanese Association for Disposal of PCBs is responsible along with local Governments for the collection and temporary storage of household electric applicances and other electrical equipment containing PCBs. The Association will develop PCB treatment technology and treatment plants for disposal, although the latter effort has been delayed by public opposition to the selection of proposed treatment plant sites.

Substitutes for PCBs that are currently in use in Japan include (1) for carbonless carbon paper, alkyl naphthalene, alkyl phenylethane, (2) for heat transfer, diphenyl, diphenylether, alkyl diphenyl, alkyl naphthalene, alkyl benzene, and mineral oil, and (3) for transformers and capacitors, mineral oil and silicone oil.

Conclusion

In conclusion, I would like to stress that EPA intends to continue to give high priority to the problems associated with PCBs. The recent data on toxicity and levels of environmental contamination have heightened our concerns and have stimulated considerable new activity.

Much is known about PCBs, and much more will be known in a few months as our current data collection efforts are brought to fruition. In recognition of the national interest in the PCB problem, and particularly the interest in the Great Lakes area, I am pleased to announce that in late fall EPA. in cooperation with other Federal agencies, will sponsor a national symposium in Chicago to further clarify selected aspects of the PCB problem. The State of Wisconsin herewith receives our first invitation to participate.

PROGRAM OF THE OFFICE OF TOXIC SUBSTANCES IN RELATION TO MICROCOSM METHODOLOGY DEVELOPMENT AND THE OTS ECOLOGICAL EFFECTS PROGRAM

Delivered by
Carter Schuth
Chemist, Chemical Testing Branch

to the
Meeting on Substitute Chemical Program
Fredericksburg, VA -- July 30-August 1, 1975

Good morning. I'd like to thank the Office of Research and Development and the Office of Pesticide Programs for this opportunity to advertise the environmental fate and effects testing program of the Office of Toxic Substances. As you may know, the several versions of the Toxic Substances Control Act currently pending in the Congress all have provisions for EPA to require certain types of test data from industry on chemicals and chemical classes in order to determine if a chemical substance presents an unreasonable risk to health or the environment. The task for us is thus not the testing of chemicals, but the description and interpretation of adequate test methodologies -- the results of which will serve as bases for decision-making as to the need for regulatory action by EPA. I would like to discuss with you this morning the part of our program which is directed toward environmental fate and effects testing. This is spelled out on the first slide. "The Office of Toxic Substances: Objective: Evaluation and Demonstration of Methods for Environmental Testing of Chemicals."

As an aside, let me elaborate a bit on the significance of environmental fate and/or effects. For reasons which are probably best described as bureaucratic or for the sake of simplicity and organization, we tend to deal with fate separately from effects -- especially in the discussion which is to follow. More emphasis seems to be placed on fate in our program at this time. This is due to our feeling that an understanding of environmental fate is essential in arriving at some estimate of the probability of observing (and causing) environmental and human health effects. (i.e. exposure). A need crying to be filled is the development and demonstration of reliable and simple screening techniques for these effects. Bear in mind that Bob Metcalf's original idea was to develop in his model ecosystem an (if you will) "white rat" for the environmental toxicologist as an appropriate laboratory model. It is not sufficient to estimate fate without some attention to possible effects. I would strongly encourage the behavioral work of the Gulf Breeze lab and others as a promising enterprise. In addition, I'd like to pass on a comment brought to my attention by John Buckley. We can all collect reams of data from any given model-- but as regulators and the regulated what is the information we need and, very importantly, what is the information we don't need?

Now, to return to my topic - I wish to discuss with you the environmental testing activities of OTS.

In support of this objective is a contract effort involving three separate but related activities--as seen on the next slide: Methodology assessment; demonstration projects; and chemical- or problem-specific information services. Whereas I want to concentrate my comments on the second topic, I will briefly make mention of the other two. A number of methodology assessments have been completed or are in the final stages of completion. These are state-of-the-art reviews involving a comprehensive literature search and review, interviews with specialists in the various fields, and evaluations by the contractor as to the usefulness and convenience of the test methodologies. The six topics on the next slide comprise a listing of the reports that have been undertaken by this program. Most have been completed and are available through the National Technical Information Service in Springfield, Virginia. I have prepared a handout with the exact title, an abstract, and information on ordering the reports. If there are insufficient copies of this for those who are interested, I will be glad to mail this information to anyone who gives me his or her name and mailing address at the end of this session. In addition to information on the methodologies for determining the environmental fate of chemicals, we are sometimes interested in knowing what information is available on the fate or effects of specific chemicals. We are also interested in keeping abreast of current developments in the various methodologies. For these services, we turn to task order contracts which can produce information and reports on a very short schedule. The next slide lists several reports under the category of chemical-specific information services. This information is gathered from the published literature, scientists working the field, and educated guesses on the part of the contractors. To date we have investigated the environmental fate of six carcinogens (as defined by OSHA) and benzene. Ongoing are studies of the environmental fate of polynuclear aromatic hydrogens, including some nitrogen heterocycles.

I'd like to turn now to the part of our program that involves model systems directly. The studies listed under parts A and B have been started under FY 75 funding. The third category is proposed for this year. Among the many criticisms of laboratory models for determing environmental fate and/or effects is the recurring charge that we know very little or nothing about the reproducibility and variability of the various systems. In response to this, we have undertaken the two studies shown in part A. Dr. Thomas Johnson of the Fish Pesticide Laboratory in Columbia, Missouri has been working for several years on what he has called a "modular food chain." This model system appeals to us as being relatively uncomplicated, inexpensive, and indicative of actual environmental conditions. I needn't mention that concentration of toxicants in food chains is of primary concern to EPA. In order to assess the modular food chain's utility in a regulatory mode, we have signed an interagency agreement with the Department of the Interior for the Fish

Pesticide Laboratory to investigate the reproducibility and variability of the modular food chain using four chemicals and various concentrations of these chemicals. By analogy, the model terrestrial-aquatic ecosystem first described by Metcalf et al. has been met with less than universal acceptance. We have signed a contract with the Illinois Natural History Survey to undertake a study of the reproducibility of that model using the same four compounds. In this way, we hope to get good comparisons of each system. The intent in this project is to better understand the two systems rather than generate new information about potentially hazardous chemicals. In fact, it can be viewed as the study of two simple and inexpensive systems using "Benchmark" chemicals. In addition to studying the reproducibility of each system with respect to the same chemicals, we are interested in assessing the utility of each system with respect to certain types of chemicals. So, we have set up criteria for the selection of chemicals in order to achieve this comparison. We wish to look at compounds which display a range of C-14 isotopes as well as being well-characterized as to possible metabolities. We have selected decachlorobiphenyl, hexachlorobenzene, di-2-ethylhexyl phthalate, and atrazine.

In addition to wanting information on the reliability of the simpler models, we ask ourselves what can they tell us about the "real world." Dr. Howard Johnson of the Michigan State University has signed a contract to study the fate and effects of two of the previously mentioned chemicals in model stream communities. These model streams have been set up in a converted fish hatchery in Paris, Michigan. They are supplied with communities of organisms and pristine water from a stream which has been diverted to flow through the concrete channels in the hatchery. Dr. Johnson and his staff will determine the fate of the chemicals in the various trophic levels of the model streams as well as observe effects of the chemicals on the organisms. Our rationale in selecting the model streams involved the belief that field studies are both very difficult and expensive. Analogies of the model stream results and monitoring data will be possible and will be useful in validation of our models and the environment we strive to protect.

It is our intention as regulators to require of industry only the necessary information on its products that is needed for responsible decision-making. It has been suggested to us that these model systems are too complicated and that the measurement of simple physical and chemicals parameters gives the same information. This is an area that we are now investigating and feel sure will fit into the program that I've described to you this morning.

The last category encompasses the utility of physical and chemical parameters to indicate the environmental fate and transport of chemicals. As we discussed yesterday, these numbers are useful

in the utilization of models being developed as well as for comparisons with "known" compounds.

Thank you for your attention.

OFFICE OF TOXIC SUBSTANCES

OBJECTIVE: Evaluation and demonstration of methods for environmental testing of chemicals

Contract Efforts in Support of Objective:

1. Methodology Assessments
2. Demonstration Projects
3. Chemical- or Problem-Specific Information Services

Methodology Assessments

- a. Survey of Industrial Test Practices
- b. Persistence and Routes of Degradation of Chemicals in the Environment
- c. Transport of Chemicals in the Environment
- d. Methods to Assess the Effects of Chemicals on Terrestrial Animal Species
- e. Methods to Assess the Effects of Chemicals on Plants

Demonstration Projects

- a. Reproducibility and Variability
  - Modular Food Chain
  - Model Ecosystem

- b. Validation Studies
  - Model Stream

- c. Physical-Chemical Measurements
  - Octanol/Water Partitioning Coefficients
  - Water Solubility
  - Vapor Pressure

Chemical- and Problem-Specific Information Services

- a. Environmental Fate of Selected Carcinogens
- b. Benzene: Environmental Sources of Contamination, Ambient Levels, and Fate
- c. Environmental Fate of Selected PNAH's
- d. Environmental Fate of Selected Aza-arenes

Environmental Fate and Effects Testing of the Office of Toxic Substances

Contracting Efforts:

I. Methodology assessments

A. Industry Survey of Test Methods of Potential Health Hazard

Nine companies selected as representing a cross section of prominent producers of chemicals were surveyed with respect to methods used to assess toxicological and environmental properties of new and existing chemicals. Four progressive levels of investigational effort depending upon extent, frequency, and nature of chemical use are identified: 1) Single or infrequent exposure -- Acute and irritation tests, 2) Occasional low-level exposure -- Short-term repeated dose, sensitization, fish and bird studies, 3) Frequent low-level, occasional high-level exposures -- Teratology, mutagenicity, metabolism, biodegradation, environmental transport studies, 4) Frequent high-level, general consumer, unavoidable exposures -- Reproduction, lifetime, carcinogenic, environmental fate, food chain studies. Factors influencing the decisions regarding the level(s) of investigation needed or the initiation of the next higher level series of studies are explored. A chemical-by-chemical assessment by competent pharmocologists, toxicologists, and chemists is still needed. Lack of a mechanism to trigger expanded levels of testing is a serious problem.

Available through National Technical Information Service (NTIS), Springfield, Virginia 22151; Accession No. PB 239-840

B. Review and Evaluation of Available Techniques for Determining Persistence and Routes of Degradation of Chemical Substances in the Environment

This report reviews and evaluates the present state of techniques which have been used to determine the environmental persistence (biological, chemical and photochemical degradation) and routes of degradation of chemicals released in the environment by human activities. The techniques that were identified were reviewed and then evaluated for their ability to simulate natural environmental conditions, convenience of procedure, time requirements, necessary equipment and reproducibility. The ultimate evaluation was based on how well the methods have worked with well-known environmental contaminants. A cost analysis of the test methods was undertaken to determine the feasibility of comprehensive screening of chemicals for environmental persistence. A relationship between chemical structure and environmental persistence is presented and some theoretical grounds for such correlations are discussed. An attempt has been made to categorize chemicals for their suitability to various test methods based on consideration of physiochemical properties, toxicity, environmental release factors, and commercial economic factors.

To be available through NTIS soon.

C. State-of-the-Art and Recommended Testing for Environmental Transport of Toxic Substances

In progress.

D. Laboratory Test Methods to Assess the Effects of Chemicals on Terrestrial Animal Species

This report presents a review of test species and methodologies utilized in toxicological research on terrestrial animals. It involved an extensive survey of available literature, interviews with toxicologists, physiologists, and ecologists, and visits to research facilities around the country. The report contains reviews of each major animal group and individual species (where specific information was available) that have been used as test subjects in past or present toxicological research programs. Suitability for use in such testing, both actual and potential, and general information relative to laboratory maintenance and possible alternative species is presented for each group. Brief synopses of general characteristics for each group and/or species are also included. Existing methodologies used in toxicological research are discussed and evaluated for their particular applicability to testing programs and general recommendations for approaches to toxicity testing, test animals, and methods are made.

Available through NTIS, Accession No. PB-241505/AS $12.00

E. Test Methods for Assessing the Effects of Chemicals on Plants

The purpose of this report is to indicate suitable test species and methods for the determination of toxicity on plants. Plant exposure to air, soil, and water contaminants have been considered. The loss of a volatile compound into the atmosphere in the form of a gas or aerosol during manufacture may indicate a potential hazard to plants via the vapor phase, thereby necessitating air pollution testing. Material was obtained both from published literature and unpublished sources. Many knowledgeable members of the scientific community were interviewed.

To be made available through NTIS.

II. Chemical- and Problem-Specific Information Services

A. Review of the Environmental Fate of Selected Chemicals

A search of the scientific literature and evaluation of such literature on the environmental fate of the following compounds has been reported: benzidine and its salts; 3, 3'-dichlorobenzidine; 1-naphthylamine; B-propiolactone; 4,4'-methylenebis(2-chloroaniline); ethyleneimine; and bis(chloromethyl)ether. Some intelligent guessing based on structural analogies for the chemicals is made where little information was available. These chemicals are known carcinogens but little is known of their environmental fate. Emphasis is placed on reporting or estimating kinetic values for potentially important pathways of degradation. In cases where no data were available, independent calculations for free radical reactivity were made.

Available through NTIS; Accession No. PB-238908/AS $3.75

B. Benzene: Environmental Sources of Contamination, Ambient Levels, and Fate

This report reviews and evaluates available information pertinent to an assessment of benzene contamination of the environment. Benzene losses from commercial (production and use) and noncommercial (automotive emissions and oil spills) sources are considered. It is estimated that of the total quantity that is released to the environment, more than half results from motor vehicle emissions. Monitoring data somewhat support this contention. Available information on the environmental persistence of benzene suggests that it degrades slowly.

To be made available through NTIS soon.

COST/BENEFIT CONSIDERATIONS AND THE TOXIC SUBSTANCES CONTROL ACT

Delivered by
Edward M. Brooks
Chief, Special Projects Branch

to the
Critical Items Workshop on Cost/Benefit Techniques of Hazardous Materials, Toxic Substances, and Solid Waste Control
Holiday Inn, Tysons Corner, Virginia
June 23, 1975

Good Morning. The agenda calls for me to discuss a number of issues which presuppose an ongoing Toxic Substances Program. Since my office, unhappily, continues to function without enabling legislation I'll depart somewhat from the prescribed format and, instead, highlight those provisions of the proposed Toxic Substances Control Act most pertinent to Cost/Benefit analysis and briefly discuss one of the more challenging aspects. If time permits, I'll also share with you my reasons for doubting -- regretfully -- that cost/benefit analyses will ever significantly inform or direct Federal health-related rulemaking, and point out that while these reasons seem to preclude the application of cost/benefit analysis in this area they also illustrate the urgent need for such application.

There are four bills presently under consideration. The Senate Commerce Committee has held hearings on S. 776 -- the most recent version of which is a Staff Draft Working Paper dated June 6. There are three bills in the House. The Eckhardt bill is the major one and is reasonably close, I understand, to the Senate version. William Brodhead has introduced a bill favored by Labor and Environmentalists, and John McCollister has introduced one favored by Industry. I will treat with the June 6 version of S. 776 -- in part because it is the most senior of the four, but mainly because it is the only one I've read.

Some of you may expect comment upon two highly publicized, widely discrepant, projected annual costs of implementing this Act -- one prepared by EPA (estimating $110 million) and one by the Dow Chemical Company (projecting a $2 billion tab). I will discuss neither of these efforts because I consider both too speculative to be relevant to our concerns here.

Turning to S. 776, let me first point out the bill's concern, stressed throughout, with cost/benefit considerations. The opening "Policy" statement, after declaring that adequate authority should reside with EPA to regulate chemical substances, then goes on to state:

> "Such authority should be exercised in such a manner as to assure technological innovation and commerce in chemical substances and products containing chemical substances are not unduly impeded ..."

This is not empty language. Both major authorities vested in EPA by this Act -- to require risk assessment data from manufacturers of specific chemicals, and to prohibit or restrict such manufacture -- are substantively linked to the concept of "unreasonable risk" which, in turn, is explicitly defined to mean:

> "... any risk associated with the manufacture, processing, importation, or distribution in commerce for a specific purpose if such risk outweighs the benefits."

There are four significant authorities vested in EPA by this bill to which cost/benefit considerations are clearly relevant:

1. to require risk assessment data from the producers of chemical substances;

2. to screen new chemical substances prior to permitting their production;

3. to regulate hazardous chemical substances; and

4. to require reports from producers regarding the nature, volume of production, and use of the chemicals produced.

The authority to require risk assessment data from producers is perhaps the most important. Section 4 directs the Administrator to prescribe "criteria for data development" to assist in determining whether the production of specific chemical substances poses an "unreasonable risk". EPA is to promulgate such criteria, within two years of enactment, for each of the 300 substances it considers potentially most hazardous. Thereafter producers must develop and submit whatever data are necessary to satisfy these criteria. EPA's authority here is broad. It may specify both the adverse effects of concern -- selecting any that may cause an unreasonable risk -- and the particular methods and tests to be used in generating these data.

In addition to specific criteria for particular substances, EPA must prescribe comparable but generic "criteria", to be applied to all new chemical substances, and to substances for which a significant new use is proposed. It is in connection with this authority that EPA is empowered to screen chemical substances prior to their manufacture or introduction in commerce. These generic "criteria" are to be promulgated within one year of enactment, and anyone proposing to produce a new chemical substance thereafter must submit the required risk assessment data, within the prescribed format and satisfying the criteria, at least 90 days prior to commencing production. The Administrator then has three options within that 90 day period:

1. he may take no action, in which case the proposed production may commence at the end of the 90 day period;

2. he may promulgate a rule prohibiting or restricting the proposed production; or

3. he may, if he deems more or different information desirable, issue an order temporarily continuing the prohibition on the proposed production until such time as EPA promulgates a new rule revising the relevant "criteria". The proposed activity then remains prohibited until the new rule is promulgated, new data satisfying the new criteria are submitted, and either the 90 day review period has lapsed or a restrictive order has been issued.

Section 6 of the bill authorizes EPA to regulate hazardous chemical substances. Whenever the Administrator concludes that any chemical substance (new or existing) other than a pesticide, drug, food or tobacco product presents an "unreasonable risk" which cannot be adequately handled under other Federal laws, he must promulgate a rule regulating that substance. Again, the options are broad. The rule may flatly proscribe production or use of the substance; limit the amount or concentration that may be produced; prohibit or limit particular distributions or uses; or prescribe conditions -- including labeling and providing instructions for use or disposal -- under which the substance may be manufactured, processed, imported or distributed.

Finally, Section 8 would enable EPA to require any producer to maintain whatever records and submit whatever reports the Administrator deems necessary, including:

1. the trade name, chemical identity, molecular structure and location of manufacture of any chemical substance produced;

2. the uses to which such substances are put;

3. the amounts produced;

4. the number of workers exposed, and levels of exposure; and

5. any health or safety data regarding the chemical substance that is being, or has been, produced by or for, or is known to, the producer.

That summarizes the relevant provisions of the Act. The cost/benefit implications of both the reporting and regulatory requirements regarding existing chemicals seem relatively straightforward. In both cases the costs and benefits are known or, at least theoretically, ascertainable. These authorities are, in this respect, comparable to rulemaking under most provisions of the Federal Water Pollution Control Act, the Clean Air Act, the Marine Protection, Research and Sanctuaries Act, the Occupational Safety and Health Act, or the Consumer Product Safety Act.

The wicket is a bit stickier regarding the screening and regulation of *new* substances. First, in assessing the implications of regulating substances that have yet to be manufactured we are necessarily reduced to *estimating* what *might be* (with respect to both costs and benefits) rather than *measuring what is*. This immediately introduces levels of uncertainty into the analysis which can soon lend an Alice-in-Wonderland quality to the exercise.

A second problem is the relatively unspecified and open-ended nature of the proposed premarket screening process. As noted above, the procedure calls for the Administrator to (1) establish the groundrules for developing and submitting risk assessment data, (2) receive and evaluate the submitted data, (3) if deemed necessary, continue indefinitely the prohibition on production in order to change the groundrules to obtain more or better data, (4) carry out a formal rulemaking procedure to modify the groundrules, (5) evaluate the new data generated and submitted in response to the new groundrules, and (6) conceivably prohibit, and *probably* restrict, the proposed activity on the basis of that evaluation. The inherent uncertainties in this process will certainly affect -- to a largely unknowable extent -- industrial research and development commitments.

In this situation, moreover, the benefits of rulemaking may be overestimated while the costs go unrecognized.

Benefits will tend to be exaggerated because of the invariable tendency to make "worst case" assumptions in the process of assessing risks in a health-related rulemaking situation -- in order to err, if at all, on the side of "safety". While reasonable men may differ as to the propriety of this tendency it is, I believe, an ineluctable aspect of health-related rulemaking. Popular opinion to the contrary notwithstanding, bureaucratic careers seldom founder on the shoals of too *much* solicitude for human health. Once these "worst case" assumptions have been formalized in a "Criteria Document" justifying and providing the rationale for a rule, the hyper-conservative nature of the premises tends to be forgotten or ignored, and the "benefits" -- those highly theoretical lives saves -- become reified.

In contrast, the significant *costs* may not even be recognized -- much less weighed in the balance -- simply because history doesn't reveal her alternatives. Cost/benefit analysis can be reasonably expected to crank in the costs of not producing those goods that are explicitly prohibited or restricted by rule. A more serious problem, and one largely ignored, is the cost associated with not producing goods as a consequence, not of explicit prohibition, but of the dampening effect upon industrial research and development due to the increased costs and risks created by the uncertainties in the rulemaking process described above. Research efforts not undertaken, and goods not produced, are not missed and are therefore not treated as costs.

A dramatic example of this problem is presented by Sam Peltzman in his study, *Regulation of Pharmaceutical Innovation: 1962 Amend-*

ments, in a discussion of hidden costs in the Food, Drug and Cosmetic Act.

> "The unequal emphasis placed on the benefits and costs of risk taking may be explained, if not excused, by the contrast between the anonymity of the beneficiaries and the visibility of the victims. A recent example, taken from Wardell, illustrates this point. He cites the case of a benzodiazepine hypnotic (nitrazepam) which was approved for marketing in the United States in 1971, but was available abroad five years earlier. One advantage of this drug over other hypnotics is its safety in overdosage. From data on foreign market penetration of nitrazepam, and U.S. deaths from overdosage from hypnotics, Wardell concludes that the 5-year delay in U.S. marketing cost over 1,200 lives. Since three times that many die from hypnotic overdosage, the specific identity of the victims of this delay will never be known.
>
> If Wardell's data are anywhere close to the mark, this one obscure incident has cost more lives than the widely publicized chloramphenicol tragedy. Wardell concludes that "introduction of a new drug that produced fatalities anywhere approaching this magnitude would be regarded as a major disaster, but the undoubted occurrence of deaths through failure to introduce a drug has so far gone unremarked". It is this fact, rather than the particulars of the case, that should temper optimistic appraisals of current regulatory policy."

In this respect, the proposed provisions for screening and regulating new chemicals under the Toxic Substances Control Act are similar to the Food, Drug and Cosmetic Act and to some provisions of the Federal Insecticide, Fungicide and Rodenticide Act -- first in that the assessment of costs and benefits, because they necessarily depend upon an estimation of the consequences of prohibiting or not prohibiting an activity that has not yet occurred, is an uncertain exercise at best; and secondly in that the relative ease of appreciating the benefits of regulation contrasts sharply with the difficulty of even discovering the costs. This is particularly so when those costs involve a gradual, cumulative disinclination to develop, manufacture and/or market new products in the United States.

While this is an extremely difficult problem it is one that should concern anyone interested in the cost/benefit equity aspects of health-related rulemaking -- because it is in this area that overzealous regulation can do the most damage.

ENVIRONMENTAL ASPECTS OF CHEMICAL USE IN WELL-DRILLING OPERATIONS

Delivered by
Farley Fisher, Ph.D.
Branch Chief for Early Warning

to the
Conference on the Environmental Aspects of Chemical Use in Well-Drilling Operations
Houston, Texas -- May 21-23, 1975

Opening Comments

Good morning to you all. I would like to welcome you to the conference on the Environmental Aspects of Chemical Use in Well-Drilling Operations sponsored by the Office of Toxic Substances of the Environmental Protection Agency, and arranged by the Research Triangle Institute for us.

I am Farley Fisher; I am the chief of the Early Warning Branch of the Office of Toxic Substances of the EPA. I would also like to introduce Mr. Frank Ayer from RTI, the conference coordinator; he is largely responsible for the arrangements we have here today. Mr. Ayer and Mrs. McGuffey, his assistant, are available to assist you with any problems you may have.

In addition, before we start, I would like to introduce at least three of your session chairmen so that you will know them. James L. Lummus, Amoco Production Company, is going to be our session chairman today. Dr. C. S. Giam of Texas A & M University will serve as chairman Thursday. And Dr. Albert J. Fritsch, Center for Science in the Public Interest, will be our session chairman on Friday.

The purpose of this conference is to explore what is known about the environmental effects of the techniques and chemicals used in various types of well-drilling operations. I think that as the program develops it will be clear that the heaviest emphasis is on drilling of oil wells, but it is not our intention to neglect other types of wells. And it certainly is not inappropriate for persons to raise points dealing with wells other than those -- brine wells or sulfur wells, for example.

We do want to talk somewhat about the commonality of technology, and also about the distinctions in technology between various types of well-drilling operations.

I hope that we have a diversity of viewpoints represented, and I hope that everybody will feel by the time we are through that they have had an opportunity to air their views.

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It is not our intention at a meeting of this type to try to resolve any of the issues which may come up, but rather merely to get them out in the open, so that they can be discussed further in private or in other fora, with the hope that within a relatively short period of time we may decide which are real issues and which are not, and for those that are real issues, decide exactly what can be done to help alleviate the problem.

The topics to be covered in the conference cover a very wide range. We are going to talk about well-drilling techniques that are used, and in some cases techniques which are proposed for use. We are going to talk about disposal problems with spent muds. We are going to talk about ground water contamination, which is a real bugaboo. And we are going to talk about regulatory attitudes, what kind of regulations exist now, and exactly what effect they are having, good or bad, and several other items as well.

Now, one can say, "Why in the world are you looking at this problem?" or "Why are you looking at this area? We do not think it is a problem, and after all, the environment is in pretty good shape. The States of Texas and Oklahoma have not fallen into the sea yet, despite the fact that people said they would."

The answer to that is that we are not sure things are quite as good as we would like. You do hear stories, from time to time, about aquifers being contaminated, about vegetation being destroyed, and various other things which could or could not be a result of well-drilling practices.

There are some very serious problems of which we are only starting to become aware in a national sense, although they have been the focus of individuals' concerns for many years.

There is the question of ground water contamination, which is a very serious thing, especially from the point of view that once it has occurred there is really very little we can do to reverse it, and that there is frequently a very long lag time between the event causing the contamination and the actual appearance of the contamination.

There is the question of the disruption of marine ecosystems, which has received up to now considerably more attention than the ground water, and which is, once again, something we do not really understand very much about.

So we feel that there are very real questions. We do not know that the answers to those are and we are not pretending we know what the answers are. We hope that what transpires here in the next 3 days will bring us a little closer to those answers.

People will also say, "We are in an energy crunch. The government is supposed to be encouraging people to drill more oil wells, drill geothermal wells, and so on. You people want a brake on this whole operation." And the response to that, which I really consider to be a rather childish objection, is that we are not trying to put a brake on anything. Our concern is to see that what is done is done in as environmentally sound a manner as possible.

No matter how serious we think our current neeeds for oil are, they pale when compared with our ultimate need for water. And we would be making a very drastic mistake if we decided to trade off oil in the short term for water in the long term. This is the kind of mistake we simply cannot afford to make.

It might be appropriate for me to spend just a few words on what we are not intending to discuss here. We have designed this conference around the operation of drilling and installing a well. It is not our intention here to get into problems associated with accidents or improper operation of a well. In other words, we are not going to get into the subject of oil spills or gas ruptures, subjects which have been treated in considerable depth at other meetings, and of which many people are well aware. In order to concentrate on what we came here for, I would ask that we try to avoid getting sidetracked on matters of this type.

I am very happy to see you all here. I am looking forward to a very profitable and educational 3 days, and I hope you are doing the same. Success of that will depend very much on all of you feeling free to contribute what you have to contribute to the discussion as it progresses.

CONFERENCE SUMMATION

I would like to make a few acknowledgments. First, to Mr. Frank Ayer and his staff at the Research Triangle Institute for their work; to our session chairmen, Jim Lummus, Dr. Giam, Pat Wennekens, and Al Fritsch for their help and cooperation; to the army of you who spoke at this symposium. I certainly learned a lot from you and hope everybody else here did the same. To a few people who were not quite apparent who were a great help to us and, in some respects, instrumental in bringing this program together, the Texas Mid-continent Oil and Gas Association, especially George Holliday and Frank Wheeler, and also the National Water Well Association and Jay Lehr; these people were extremely helpful to us in locating and corralling people to present papers here at this conference. And, also, to the Shamrock Hilton for their facilities and the help of their staff. And, finally, but perhaps most importantly, thanks to all of you who participated from the floor, raised a lot of questions and good points, and kept a lot of people honest. What we were trying to do is get a lot of things out and I think we have done that.

There are a few things which might be worth saying. I am in a job of trying to find where the bones are buried in the pollution business. I know that makes me very unpopular with a lot of people; they tend to look at me as kind of a prosecutor or witch hunter or something. But let me say that we have real environmental problems and we really do not have to go around inventing new ones.

I think we have had a lot of very good discussions here. I am inclined to agree that we did not really see any data that caused anyone immediate alarm. There were some if's and but's and maybe's. Maybe some of these need to be looked at further. I am not going to discuss them because I have to ruminate on them before I decide things like that. But on the whole, I think we are finding an industry which, at least, knows what good practice is. And I hope it is working hard to attain it. There seems to be a case to EPA for not butting in on this matter. The States and the Geological Survey, seem to be pretty much on top of this field, doing their best to regulate it. One has to wonder why we need another bull in the arena.

I was also struck by a couple of other things. One is that we avoid accepting simple answers to what are complex questions. And I must say, I am not sure what an LC_{50} on trout means in terms of environmental damage. I am not sure I would want to say anything regarding safety or danger on the basis of a test like that. Environmental harm is much more complex than killing a few trout. And I think that we cannot hope in the near future to invent a few very simple things that we can do and get a magic answer that says: "Yes, this is safe; no, this is not safe." We are going to have to take chances for a long time to come. And we are always going to have to watch what we do, especially when we start doing something new.

This, of course, is not an excuse for not being careful about the new things that we do, and not trying to reason ahead about what their implications might be. Which leads to another point; namely, that we must also remember that theory is no substitute for experiment and experience. The fruit of the pudding is in the eating. If the ground water is drinkable even after years and years of drilling in an area, there is a very good argument for the fact that the practices used in drilling were not upsetting the water.

However, we are drilling in new places all the time. And it is certainly true, as many of you have pointed out, that we are using new techniques all of the time. So the fact that we did things right 50 years ago does not mean that we are doing them right today. So we do have to be on the lookout and be on our guard.

I hope all of you have found this meeting as stimulating, as interesting, and as informative as I have. I want to thank you for your patience.

At this point I will throw the floor open for some general discussion if anybody wishes to make some closing comments.

Mr. Robert B. Allred (Sun Oil Company, Richardson, Texas): Environmental Canada, I just want to point out one thing. I would not drink concentrated sodium hydroxide. I would not drink concentrated hydrochloric acid. However, if they were mixed together at the proper end-points, I would gladly drink them.

Mr. Dennis G. Wright (Environment Canada, Winnepeg, Manitoba, Canada): Point taken. Granted, there are a lot of common everyday chemicals and things that occur naturally in the earth that are used in drilling fluids. But there are also an awful lot of synthetic materials that are used as well.

Mr. Allred: But give them mixed together, do not give them individually. I do not use an individual mud. I use a mixture of things for the mud, not the individual products.

Mr. Wright: Right. But when you are looking at that, how can you separate the effects of a thinner or disperser, for example, from potassium chloride or caustic or something like that? You cannot do that in the hole mud. You have to do it individually.

Mr. Allred: But the environment does not come in contact with lignosulfonate, for instance. The lignosulfonate goes into the clays and to the other chemicals. It is not sodium chromium lignosulfonate anymore. It has changed.

And as the good doctor pointed out, you put the pressure and heat in that oil well and you have got a good kettle for a lot of things that come out. And some of them, I might point out, may be worse than the individual materials themselves.

So look at it like it is. I just do not dump caustic in water; it is mixed in the mud.

General Chairman Fisher: I thank you. And this conference is now adjourned.

RISK ANALYSIS AND SETTING STANDARDS FOR CHEMICAL CARCINOGENS

Delivered by
Michael J. Prival, Ph. D.
Acting Chief, Chemical Testing Branch

to the
Washington Statistical Society Meeting
Bethesda, MD -- April 23, 1975

A brief review of some recent Federal actions relating to the control of chemical carcinogens may help to put into perspective the usefulness of statistical extrapolation of risk. I will restrict my discussion to carcinogens, although the methods for risk extrapolation which have been discussed today may be applicable to other toxic effects as well. A discussion of the diverse methods by which Federal agencies have regulated chemical carcinogens should make it clear that the usual regulatory response to a newly discovered carcinogen is confusion. Statistical approaches to risk analysis may help us to find our way out of this confusion, but so far they have, if anything, only been a part of it. This is not because the methods are not valuable, but rather because we have not yet learned what their value is and, more importantly, what their limitations are.

Any discussion of Federal regulatory policy on carcinogens must begin with the Delaney clause of the Federal Food Drug and Cosmetics Act. This clause states that chemicals which meet certain criteria of carcinogenicity cannot be used as food additives. In spite of all of the furor concerning this clause, it is interesting to note that since its introduction in 1958, it has been invoked only twice to ban food additives and both of these were trivial components of food packaging.

It has been argued, however, that the Delaney clause represents a bad regulatory principle. For example, this clause might require the FDA to immediately prohibit the use of food packaging containing vinyl chloride if it became convinced that vinyl chloride is a carcinogen by ingestion. Since much of the plastic food packaging used today contains vinyl chloride, this might be a serious economic problem. Statistical approaches to estimating "virtually safe" doses might help FDA out of this bind, but this would be in conflict with the Delaney clause.

Mantel and his colleagues have pointed out that a blanket requirement to ban all carcinogens as food additives provides a strong incentive for manufacturers to fail to perform adequate experiments which might demonstrate carcinogenicity. The Mantel-Bryan procedure is a method for estimating "virtually safe" or "acceptable" levels of chemicals independent of whether or not the chemical is found to be a carcinogen. Acceptance of the Mantel-Bryan method thus would remove the strong regulatory response which now must follow any significant positive finding of carcinogenicity. This, it is claimed, will create an incentive to industry to increase doses and numbers of animals in the hope of obtaining higher permitted use levels of additives in food. The principal problem with this reasoning is the fact that regulatory agencies will not, in my judgment, set standards for non-carcinogenic chemicals as if they were carcinogens. I believe that chemicals will continue to be placed in two classes, carcinogens and presumed noncarcinogens, with different regulatory principles applied to each. If this is correct, then one of the important assumptions behind the use of the Mantel-Bryan method is invalid.

The first regulatory attempt to use the Mantel-Bryan method was in July 1973, when the Food and Drug Administration proposed using it for determining the concentrations of carcinogenic chemicals which the analytical chemists must be able to detect before use of these chemicals in food-producing animals would be permitted. The calculated risk level proposed for determining this concentration was one per hundred million.

Five months after the FDA proposal, the Environmental Protection Agency also proposed using the Mantel-Bryan method, this time to assist in setting a standard for the known human carcinogen benzidine, which is used in making dyes. This proposed standard, which would limit the discharge of benzidine into the water, was based on a calculated risk limit of one in a million rather than one in a hundred million.

One major criticism which has been leveled at the EPA proposal is that we have not clearly established that benzidine provides substantial benefits to society and therefore we should not permit any exposure at all. While there is merit to this criticism, it is not clear to me how a zero discharge standard would be enforced since the limit of chemical detection is relatively high. Another problem with a zero discharge standard is that it would, in effect, prohibit the use of benzidine in making dyes and there is evidence that some of the chemicals likely to replace benzidine are themselves carcinogenic.

An alternative to setting standards for carcinogens either at "zero" or at some arbitrary calculated limiting risk level is to make the standard as stringent as is technically and economically feasible. A number of regulatory actions involving carcinogens have been based almost solely on such technical considerations. In April 1973, the Environmental Protection Agency, armed with neither a suitable analytical method nor any appropriate dose-response data, set limitations on the release of asbestos by stating simply that: "There shall be no visible emissions to the outside air". In addition, certain work practices designed to reduce the dispersal of asbestos into the air were required, such as wetting and removing asbestos insulation before demolition of a building. No numerical standard or risk estimates were possible.

The Food and Drug Administration, in addition to its reponsibilities for regulating food additivies, must also attempt to protect us from carcinogens which appear naturally in our food. These substances are not covered by the Delaney clause. Aflatoxins, for example, are caused by a mold which grows on peanuts. Initially, the FDA set standards for aflatoxins at the limit of chemical detection, but now the chemists have improved the analytical methods to the point that perhaps 25% of our peanut butter would have to be confiscated if the detectability rule were still applied. Therefore, the FDA has proposed a maximum permissible level of aflatoxins in peanuts of 15 parts per billion, recognizing that when 25 rats of one strain were fed diets containing aflatoxin B-1 at this same concentration, which is now permitted in peanuts, every one of them contracted carcinoma of the liver. Clearly, the present standard is based at least as much on practicality as it is on assessment of risk.

In January of 1974, the Department of Labor issued regulations on 14 carcinogens in the workplace. These regulations are based solely upon the technical feasibility of limiting worker exposure while permitting continued use of the chemicals. The standards simply specify work practices, such as adequate ventilation and the use of protective clothing, which must be followed when these carcinogens are present. Again no numerical limits on exposure were set.

The Department of Labor has also promulgated a regulation limiting the concentration of vinyl chloride in the workplace to 1 part per million. The fact that vinyl chloride has been shown to cause cancer in laboratory animals exposed to 50 ppm clearly indicated that the 1 ppm standard is not based upon any concept of "virtual safety" or even a calculation of "acceptable risk." The Department of Labor standard also has the provision that vinyl chloride must be reduced to the lowest feasible levels if the 1 ppm standard cannot be met. This is because the Government could not really determine in advance what levels would be feasible for industry to achieve.

I could give further examples, but the point I am trying to make is that technological and economic feasibility very often will limit the utility of risk analysis in writing regulations.

Although there are good arguments in favor of setting standards for carcinogens at the lowest "feasible" level, feasibility can be a slippery concept. When we ask the engineers how low they can bring emissions or effluents, they often turn around and ask us what level we want and how much we are willing to spend. Feasibility often boils down to acceptable cost, and the judgment of what costs are acceptable depends solely on who is making the decision.

In principle, of course, we would want to take into account both the risks and the costs of control and somehow balance these to achieve the best solution for society as a whole. This requires that the methods for risk analysis be used not only to estimate a "virtually safe" dose, but also to provide us with risk estimates at doses above those which are "virtually safe." This, of course, is a much more difficult task and we are faced with the serious problem that when we present intermediate risk estimates to administrators they tend to take them seriously. One of the dangers of statistical approaches to estimating risk is that they provide us with enticing numerical answers which appear to be far more accurate than they are.

It has been said that attempts to set standards by an explicit balancing of risks against costs may simply be a tactic for preventing enactment of stringent regulations. It has been argued that the balancing of tenuous risk estimates against even less solid cost estimates only provides sophisticated excuses for regulatory inaction. We do not yet have enough experience with risk-cost-benefit analysis to know whether these fears are legitimate.

Do we need better methods for extrapolating risk? Yes--Particularly for distinguishing "conservative" from "most likely" estimates of risk.

More significantly, however, we lack the wisdom of knowing how to use these methods in designing regulations. We will only gain this wisdom through experience, and the learning process we are going through is painful. As more chemicals are found to be carcinogenic, we will make many more mistakes. This will inevitably result in the unwarranted overregulation of some carcinogens and the unconscionable underregulation of others.

ENVIRONMENTAL ASPECTS OF CHEMICAL USE IN RUBBER PROCESSING OPERATIONS

Delivered by
Farley Fisher, Ph.D.
Branch Chief for Early Warning

to the
Conference on Environmental Aspects of Chemical Use in Rubber Processing Operations
Akron, Ohio -- March 12-14, 1975

Welcoming and Introductory Remarks

Welcome to this conference on environmental aspects of chemical use in rubber processing. This is the first conference of this type sponsored by the Office of Toxic Substances, and we hope it is is the prototype for conferences on a number of other industrial operations as well. Our object here is to discuss the use of chemicals in rubber processing -- to analyze where these materials may have an effect on the environment, either because of the substances used in the process or because of the types of products produced therein. We are definitely doing this with an attitude of exploration and debate, and we wish for the conference to be lively. In no sense are we trying to restrain people from expressing their views. We have allowed for a large number of question and answer periods and I hope that you will avail yourselves of the opportunity to ask questions and make comments.

Our keynote speaker for this meeting is Mr. Glenn Schweitzer, who has been Director of the Office of Toxic Substances for about 2 years now. During that period of time, Mr. Schweitzer has been actively involved in the Toxic Substance Program at EPA.

CONFERENCE SUMMATION

General Chairman Fisher: Our plan at this point is to give each of the session chairmen 5 to 10 minutes to comment on his session or on the rest of the conference. Unfortunately, two of our session chairmen are not with us today because of other commitments. Mr. Robert C. Niles of Uniroyal, Inc., Chairman of Session I, had planned to be here but unfortunately could not. Mr. David Garrett of the Office of Toxic Substances at EPA in Washington was to substitute for Mr. Niles, but he too was unable to attend today. However, Session I was very informative, especially concerning the techniques for controlling odor problems and effluent problems.

Mr. William E. McCormick of the American Industrial Hygiene Association was also unable to be here today, and I have asked Dr. George Levinskas to substitute for him at this time. Dr. Levinskas is eminently qualified to serve in place of Mr. McCormick. He is an industrial hygienist with experience in occupational health, and currently holds the position of Manager of Environmental Assessment and Toxicology for the Monsanto Corporation.

Dr. George J. Levinskas (Monsanto Corporation, St. Louis, MO): The sessions have ranged quite widely from experimental toxicity tests on animals, to clinical observations of human health, to chemical and physical studies measuring various parameters dealing with some phase of making or using rubber.

One of the speakers made a passing reference implying that animal toxicity data had no relationship to and limited value for the assessment of the effects of chemicals on man. I must take strong exception to that remark. Test data obtained by exposing animals to chemicals are useful in predicting their probable effects on man. There may be many difficulties in evaluating the low incidence of a given finding in animals. This is a situation comparable to the difficulties an analyst has in detecting a peak in a tracing when it is not much above the background noise generated by his instrument. There may be uncertainties as to the relative susceptibility of man versus the animals for a given material. There are many other problems in evaluating potential risk to man from exposure to a given substance as judged by animal studies. However, despite the real and sometimes imagined drawbacks to animal tests, these tests have been, are now, and will continue to be useful in evaluating the health effects of chemical substances on man.

Several of the papers point up the need for the measurement of materials, qualitatively and quantitatively, in the environment. We need to know what, and how much, is out there before we can begin to assess the potential hazards to man or to the environment of these various materials. However, because of today's technology, chemists have exceedingly powerful analytical tools at their disposal. We should remember that, while discovery of a new contaminant raises a question as to its significance, it does not necessarily portend doom or gloom. In fact, under different conditions, a similar situation may be either bad or good. A used tire dumped in a lake or settled on the bottom of a swimming hole represents undesirable litter. The same tire sunk in an estuary becomes a beneficial, artificial reef. The reason we judge one situation to be bad, and the other to be good, is based either on our personal experience or on our prior conditioning to accept a belief.

It has been remarked at this conference that researchers do not like to publish negative data, i.e., data supporting safety. Researchers prefer to publish findings. I have no quarrel with that view. However, we should be attempting to define those areas in which there could be a high probability of risk. This requires objective reporting of data. The use of overtones and innuendos to imply that imminent disaster is coupled with every finding of a new environmental contaminant, no matter how small its concentration may be, is misleading. It can only confuse the litter tire and the reef tire.

Mr. J. R. Laman (The Firestone Tire and Rubber Company, Akron, Ohio): Our group in environmental engineering and I are sure that other environmental engineering groups in major corporations are consistently seeking to strengthen the interface with toxicology, industrial medicine, and industrial hygiene. I feel that a major item for consideration was left out of this conference; namely, no one talked about the double line. Unfortunately, no attempts were made to equate cost/benefit/risk with quality of life, or lifestyle. When we talk about this lunch counter business, it involves everybody. Somebody has got to pay the costs.

My field is strictly the engineering approach; for example, in a water problem, we get down to specified levels and then make an ecological judgment of the system. We fine-tune as required. We strike a good cost/benefit/safety balance. We must never forget that our pollution control approach must be tuned to the highly developed nations, which are competing for our markets and services. The highly developed nations must embrace pollution control as a cost of doing business, as we are doing, to compete fairly. By juggling the equation, some component of the equation will be affected.

Let me repeat it again: cost/benefit/risk equals quality of life, or lifestyle.

Since we have the highest standard of living that humanity has known, we must prudently chart our course; because if we do not, it will be unfairly taken off the top.

The environmental engineers in this very worthwhile conference offered to us many pollution-free ways of disposing of tires. Tires can be properly disposed of in incinerator boilers, fish reefs, and conventional reclaim.

At this time, we should look at the economical feasibility of all the disposal technologies just discussed as well as other technologies just emerging, which are described in the literature. By balancing the cost/benefit/risk ratio with economics, I am sure that we can find a suitable solution for the disposal of these tires without adversely affecting the ecosystem. In conclusion, we must determine who is going to pay the price.

General Chairman Fisher: Mr. Beliczky, do you have some more remarks?

Mr. Louis S. Beliczky (United Rubber Workers International Union, Akron, Ohio): All of us know our moral and social responsibility in the area of air pollution. Organized labor's role in air pollution problems has been minimal to date. We have probably been more concerned about the workers' in-plant environmental health problems than about out-plant emissions.

We must have an awareness of the serious hazards from air and water effluents to the population in general. A few months ago a news release implicated increased birth malformations to areas along Lake Erie where polyvinyl chloride resin manufacturing plants were located: Avon Lake, Painesville, and Ashtabula.

EPA reports conducted in 1974 indicated that vinyl chloride was found by air and stream emission studies in the areas implicated. No real scientific studies to date have directly implicated vinyl chloride to the increased incidence of birth malformations. Before positive judgments are made, more objective studies must be conducted, keeping in mind that at each site mentioned, power-generating plants have been also operating for many years.

We must be concerned that four carcinogens have been identified as being present in the carbon black actually used in the rubber industry. The fact that we are beginning to identify some of the chemicals being produced in rubber curing processes must be emphasized. Dr. Rappaport's presentation and studies being conducted by Harvard may lead us to an identification of specific causative factors producing the many forms of cancer which were mentioned by Dr. Harris and Professor Burgess.

Greater emphasis must be placed on morbidity studies so necessary to follow up on the mortality (epidemiological) data. Only through joint and concerted investigations can we hope to succesfully control the hazards to which our workers are exposed. The workers themselves negotiated the $10.20 per year that is set aside for the university studies.

Each segment of specialized studies will eventually lead to that safe and healthful work environment to which each working man and woman is entitled. Perhaps the data will assist in controlling the whole system--his environmental health at work and away from the job.

I must respond to the statement of relating animal toxicity data to human beings. I can only state that if a material has been proven to be carcinogenic to animals, but no data are available to document it as a causative agent in producing human cancer, it cannot be dismissed as being safe for human beings.

This philosophy has been capriously applied to vinyl chloride and to 2, 4, methylene-bis-2-chloroaniline (MOCA) by those who hold the dollars and cents of profit over lives.

Indiscriminate judgments regarding workers' health are sometimes made by the uninformed and callous decisionmakers. Who really pays? It is mainly the workers who pay from their pockets and/or with their health or lives.

Dr. Fisher: The questions are: What are the problems, and where can we take these problems to make progress? We are limited; we are merely mortals and we cannot do everything at the same time.

What are the areas we have to move into first to identify and then control those things that are the greatest threat to our health and our environment? These are the kind of things I think we are trying to get at here, as they concern all of us. At the same time, it is important not to get so hung up with talking about what we were going to do that we do not actually make progress.

I hope that having this meeting and these discussions have stimulated people to think in the areas where they had perhaps not thought before, because of ignorance, not because of intent. I hope you all learned something; I know I have certainly learned a lot here from all of you and I appreciate it very much.

TOXIC CHEMICALS REGISTRIES IN THE UNITED STATES

Delivered by
I. Eugene Wallen, Ph.D.
Deputy Director, Office of Toxic Substances

to the
Bilthoven Meetings
Geneva, Switzerland - January 6, 1975

The United States does not have a consolidated registry of information on hazardous substances. More than twenty-two Agencies of the Federal Government as well as State and local governmental units have data files for one purpose or another. Additional data may be stored by industry, by group of industries, or by other private organizations. A directory of Environmental Information Systems in the Environmental Protection Agency lists 146 data systems (21 air, 22 pesticides, 19 radiation, 4 solid wastes, 59 water, 21 general) that may contain data on toxic chemicals.

The development of information about the hazard of chemical substances has been responsive to the operational problems of occupational exposure; containment and packaging; contamination of foods, water, or air; control of spills, etc., rather than to the basic nature of the substances. The United States approach has been to provide data oriented to the specific potential problem, rather than to store information by substances. The existing lists have been prepared to meet localized issues rather than to resolve national or international problems.

The most comprehensive listing of toxic substances in the U.S. is that of the National Institute for Occupational Safety and Health, which Dr. Herbert E. Christensen will report on. A report will be published within the next few months by the National Academy of Sciences called Water Quality Criteria. A 2 volume report, volume 1 will consist of criteria arranged alphabetically by water use with the limits for each pollutant followed by the supporting scientific justification. Volume 2 will provide information on the sources of polluting constituents, their mean levels in major river basins, techniques for biological and physical measurements, methodology for bioassays, the overall classification of water quality, and the types of pollutants suitable for maximum daily load measurements.

Currently there are no plans for the development of an overall registry in the United States. There would be great difficulty in developing a proper U.S. contribution to a common registry. Among the negative aspects of this proposal are (1) problems and expense to the U.S. in acquiring, updating, and formatting the data, (2) evaluating the accuracy and completeness of the data, (3) considerations of extent of use of such a registry, if established, (4) problems of data management in the US system, and (5) reluctance of indus-

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try to provide significant data that might compromise international trade.

A modest UN referral service has been suggested as a reasonable alternative to the registry. Such a referral service might be a forerunner of a registry or an end in itself. For the immediate period it may be the only feasible way for the UN to obtain appropriate input into the U.S. multiple files of data.

High Volume Chemicals

As an example of the complexity of the problem I would like to review recent work by my office in following up the Vinyl Chloride carcinogenicity problem. It was determined to make a preliminary examination of the fifty highest volume chemicals with respect to the way agencies reflect an interest in them. The May 6, 1974, issue of Chemical and Engineering News had listed these chemicals (Table 1) by rank in production volume and in comparison of 1973 with 1972 production.

Table 1 -- The Top 50 Chemicals in Production Volume in the United States

Rank 1973	Rank 1972^{a}		PRODUCTION (Billions of pounds) 1973	1972^{a}	PRODUCTION (Common units^{b}) 1973	1972^{a}	AVERAGE ANNUAL CHANGE 1972–73	1971–72	1968–73	1963–73
1	1	**Sulfuric acid**	63.18	62.60	31,588 tt	31,300 tt	0.9%	7.8%	2.0%	4.2%
2	3	**Oxygen,** high and low purity	31.87	29.22	385 bcf	353 bcf	9.1	10.7	9.2	11.6
3	2	**Ammonia,** synthetic anhydrous	30.94	30.39	15,468 tt	15,193 tt	1.8	4.5	5.0	8.7
4	4	**Ethylene**	22.41	20.85	22,405 mp	20,852 mp	7.4	13.0	11.3	11.5
5	5	**Sodium hydroxide,** 100% liquid	21.36	20.43	10,678 tt	10,217 tt	4.5	5.7	3.8	6.3
6	6	**Chlorine,** gas	20.60	19.75	10,302 tt	9,873 tt	4.3	5.6	4.1	6.6
7	9	**Nitrogen,** high and low purity	16.38	14.06	226 bcf	194 bcf	16.5	15.5	13.7	16.1
8	8	**Sodium carbonate,** synthetic and natural	14.99	14.88	7,496 tt	7,439 tt	0.8	4.0	2.5	2.6
9	7	**Nitric acid**	14.86	15.96	7,430 tt	7,981 tt	−6.9	4.5	1.2	5.8
10	10	**Ammonium nitrate,** original solution	13.89	13.76	6,943 tt	6,881 tt	1.3	3.7	3.9	5.7
11	11	**Phosphoric** acid, total	13.00	13.06	6,498 tt	6,531 tt	−0.5	9.4	4.3	8.4
12	12	**Benzene,** all grades	10.65	9.18	1,453 mg	1,252 mg	16.1	16.4	7.8	8.4
13	14	**Propylene**	8.76	8.47	8,764 mp	8,472 mp	3.4	22.9	4.5	12.4
14	13	**Ethylene dichloride**	7.90	8.60	7,903 mp	8,600 mp	−8.1	13.8	10.5	16.0
15	15	**Urea,** primary solution	7.12	6.95	7,120 mp	6,950 mp	2.4	9.2	7.9	12.4
15	18	**Methanol,** synthetic	7.12	5.96	7,118 mp	5,956 mp	19.5	20.3	13.3	11.8
17	16	**Toluene,** all grades	6.78	6.63	936 mg	916 mg	2.2	4.6	6.1	8.7
18	17	**Ethylbenzene**	6.50^{c}	6.43^{c}	6,500 mp^{c}	6,425 mp^{c}	1.2	28.9	10.0	10.2
19	20	**Formaldehyde,** 37% by weight	6.17	5.65	6,173 mp	5,650 mp	9.3	24.9	7.5	9.3
20	19	**Styrene**	6.01	5.95	6,014 mp	5,950 mp	1.1	27.1	10.2	10.8
21	21	**Xylene,** all grades	5.90	5.33	818 mg	739 mg	10.7	20.8	8.8	9.3
22	22	**Vinyl chloride**	5.35	5.18	5,348 mp	5,175 mp	3.3	19.3	12.5	14.1
23	23	**Hydrochloric acid,** total	4.78	4.60	2,389 tt	2,302 tt	3.8	9.7	6.5	8.5
24	25	**Ammonium sulfate**	3.97	3.72	1,985 tt	1,858 tt	6.8	2.0	−0.2	5.1
25	24	**Ethylene oxide**	3.88	3.95	3,875 mp	3,950 mp	−1.9	9.8	8.1	7.5
26	26	**Butadiene (1,3-),** rubber grade	3.66	3.53	3,663 mp	3,527 mp	3.9	5.6	4.5	4.7
27	28	**Carbon black**	3.50	3.21	3,500 mp	3,210 mp	9.0	6.1	4.5	5.4
28	27	**Ethylene glycol**	3.29	3.30^{c}	3,290 mp	3,300 mp^{c}	−0.3	7.5	10.0	7.1
29	30	**Sodium sulfate,** high and low purity	2.85	2.65	1,424 tt	1,327 tt	7.3	−2.2	−0.8	1.5
30	29	**Carbon dioxide,** all forms	2.77	2.96	1,387 tt	1,481 tt	−6.3	10.2	5.6	3.6
31	38	**Dimethyl terephthalate**	2.69^{c}	2.06^{c}	2,690 mp^{c}	2,055 mp^{c}	30.9	18.2	15.5	23.7
32	32	**Cumene**	2.67	2.38^{c}	2,665 mp	2,380 mp^{c}	−12.0	11.0	14.6	19.9
33	39	**Terephthalic acid**	2.49^{c}	2.02^{c}	2,490 mp^{c}	2,015 mp^{c}	23.6	27.4	21.2	na
34	36	**Acetic acid**	2.42	2.15^{c}	2,419 mp	2,150 mp^{c}	12.5	9.9	6.8	8.9
35	33	**Calcium chloride,** solid and liquid	2.40^{c}	2.34	1,200 tt^{c}	1,169 tt	2.7	−3.7	0.7	2.7
36	34	**Cyclohexane**	2.35	2.29^{c}	2,354 mp	2,285 mp^{c}	3.0	30.7	2.9	8.1
37	35	***p*-Xylene**	2.32	2.20	2,315 mp	2,200 mp	5.2	32.4	12.0	24.3
38	31	**Aluminum sulfate,** commercial	2.27	2.51	1,136 tt	1,256 tt	−9.6	5.5	−0.6	1.8
39	40	**Phenol,** total	2.25	2.00	2,249 mp	1,995 mp	12.7	11.8	8.2	9.2
40	43	**Acetone**	1.99	1.76	1,987 mp	1,759 mp	13.0	14.4	7.8	7.7
41	41	**Ethanol,** synthetic	1.97^{c}	1.87^{c}	1,965 mp^{c}	1,870 mp^{c}	5.1	14.7	−1.7	0.1
42	37	**Sodium tripolyphosphate**	1.83	2.07	914 tt	1,033 tt	−11.5	−0.7	−5.0	1.2
43	42	**Isopropanol**	1.76	1.85	1,755 mp	1,850 mp	−5.1	7.5	−3.3	1.8
44	45	**Propylene oxide**	1.75	1.51	1,753 mp	1,513 mp	15.9	26.7	12.8	13.4
45	44	**Acetic anhydride**	1.55	1.56	1,550 mp	1,560 mp	−0.6	3.2	−1.5	2.0
46	46	**Titanium dioxide**	1.54	1.44	772 tt	718 tt	7.5	5.9	4.3	4.0
47	50	**Vinyl acetate**	1.48	1.20	1,483 mp	1,204 mp	23.2	29.3	15.6	13.9
48	48	**Sodium silicate (water glass)**	1.46	1.32	730 tt	661 tt	10.4	3.9	2.9	2.8
49	49	**Acetaldehyde**	1.40^{c}	1.30^{c}	1,400 mp^{c}	1,300 mp^{c}	7.7	−12.8	−2.5	2.0
50		**Acrylonitrile**	1.35	1.12	1,353 mp	1,115 mp	21.3	13.9	5.8	11.5

a Revised. b tt = thousand tons, bcf = billion cubic feet, mp = million pounds, mg = million gallons. c C&EN estimate. na = not available. **Sources:** Bureau of the Census, Bureau of Mines, and Tariff Commission

On a draft basis, matrices have been developed that reveal a portion of the interest of U.S. Agencies in control of these 50 chemicals. These matrices will have been modified during the interim between preparation of this paper and the meeting itself; however, they appear to be of value even in their current status. Table 2 lists the 50 highest volume chemicals in relation to the various Offices of the EPA. The X marks in the table mean that some type of activity is taking place, be it regulation or a firm plan to obtain information.

Table 2 -- Activity Checked by EPA Office with Reference to 50 High Volume Chemicals

	Oil and Hazardous Materials					
Chemical Name	Effluent Guidelines FWPCA	Proposed Rules	Technical Data Available	Pesticides	Clean Air	Research and Development
Sulfuric Acid	X	X		X	X	X
Oxygen			X			X
Ammonia	X		X			X
Ethylene	X		X	X	X	X
Sodium Hydroxide	X	X	X	X		
Chlorine	X	X	X	X		X
Nitrogen	X		X			X
Sodium Carbonate	X		X	X		
Nitric Acid	X	X	X			
Ammonium Nitrate	X	X	X			
Phosphoric Acid	X	X	X	X		
Benzene	X	X	X	X	X	
Propylene	X		X		X	X
Ethylene Dichloride	X		X	X	X	X
Urea	X		X			X
Methanol	X		X	X		
Toluene	X	X	X		X	X
Ethylbenzene	X	X	X		X	X
Formaldehyde	X	X	X	X	X	X
Styrene	X	X	X		X	X
Xylene	X	X	X	X	X	X
Vinyl Chloride	X		X		X	
Hydrochloric Acid	X	X	X	X		
Ammonium Sulfate	X	X	X	X	X	
Ethylene Oxide	X		X	X	X	X
Butadiene	X				X	X
Carbon Black			X		X	
Ethylene Glycol	X		X	X		X
Sodium Sulfate	X		X		X	
Carbon Dioxide	X		X			
Dimethyl Terephthalate	X				X	X
Cumene	X					
Terephthalic Acid	X					
Acetic Acid	X	X	X			
Calcium Chloride	X		X		X	
Cyclohexane	X	X	X		X	X
p-Xylene	X		X		X	X
Aluminum Sulfate	X	X	X		X	
Phenol	X	X	X	X		
Acetone	X		X		X	X
Ethanol	X			X		
Sodium Tripolyphosphate	X			X	X	
Isopropanol	X			X	X	
Propylene Oxide	X			X		
Acetic Anhydride	X	X	X		X	
Titanium Dioxide	X		X		X	
Vinyl Acetate	X	X	X			
Sodium Silicate	X	X	X		X	
Acetaldehyde	X	X	X			
Acrylonitrile	X	X	X	X		X

The effluent guidelines column in the matrix refers to regulations issued under authority of the Federal Water Pollution Control Act, as amended. The regulation of a given substance is based on the water quality of its effluent considering total suspended solids, biochemical oxygen demand and/or other selected characteristics (pH, temperature, chemical oxygen demand, reductions of certain chemicals, etc.), depending upon the industry.

The Oil and Hazardous Materials column refers to substances designated as "hazardous substances" as authorized under the Federal Water Pollution Control Act. The first column involves direct control while the second column refers to an information base which was developed to assist in cleaning up after a hazardous substance spill.

The pesticides column lists the chemicals which are registered under the Federal Insecticide, Fungicide and Rodenticide Act. Any chemical so registered must have been studied in evaluation of hazards to humans and to other components of the environment. Only that portion of the production of a chemical that enters into the pesticide market could be controlled under this Act.

The Clean Air Act provides broad authority to control air quality. Source performance standards, primary and secondary ambient air quality standards, and regulations of new stationary source emissions are promulgated for control of releases of particulates and hydrocarbons.

The EPA Office of Research and Development carries out investigations concerning toxicological effects of pollutants on aquatic and terrestrial plants and animals, on human health consequences of releases of chemicals, towards the development of methods for high quality measurements of the occurrence of toxic substances in the environment, and in gathering data on environmental levels of chemicals and their persistence.

Non-EPA Activities

Outside the Environmental Protection Agency several U.S. agencies are involved in studies of the high volume chemicals. Some of these agencies have programs included in Table 3 (below) and described in the following paragraphs.

The National Cancer Institute publishes a survey of compounds which have been tested for carcinogenic activity. Although the latest data in the current survey are 1971, a cursory attempt has been made to determine whether additional chemicals from the top 50 list have been tested since then. In addition to the human data a national registry of animal tumors is maintained. An international group of experts in chemical carcinogenesis meets periodically to evaluate the carcinogenicity of individual chemicals.

Table 3 -- Activities in Agencies other than EPA with Reference to 50 High Volume Chemicals

Chemical Name	National Cancer Institute	Dept. of Transportation	HEW		Dept. of Labor
			FDA	NIOSH	OSHA
Sulfuric Acid	X	X		X	X
Oxygen		X		X	
Ammonia	X	X		X	X
Ethylene			X	X	
Sodium Hydroxide	X	X		X	X
Chlorine		X	X	X	X
Nitrogen		X			
Sodium Carbonate		X		X	
Nitric Acid	X			X	X
Ammonium Nitrate		X		X	
Phosphoric Acid		X		X	
Benzene	X	X		X	X
Propylene		X		X	
Ethylene Dichloride	X	X	X	X	X
Urea	X	X	X	X	
Methanol		X		X	
Toluene	X	X		X	X
Ethylbenzene	X	X		X	X
Formaldehyde	X	X	X	X	X
Styrene	X	X	X	X	X
Xylene	X	X		X	X
Vinyl Chloride	X	X	X	X	
Hydrochloric Acid	X	X	X	X	
Ammonium Sulfate	X			X	
Ethylene Oxide	X	X	X	X	X
Butadiene		X		X	X
Carbon Black	X		X		X
Ethylene Glycol		X		X	X
Sodium Sulfate			X	X	
Carbon Dioxide		X		X	X
Dimethyl Terephthalate				X	
Cumene		X		X	X
Terephthalic Acid				X	
Acetic Acid	X	X		X	X
Calcium Chloride	X			X	
Cyclohexane	X	X		X	X
p-Xylene		X		X	
Aluminum Sulfate				X	
Phenol	X	X	X	X	X
Acetone	X	X		X	X
Ethanol	X	X		X	
Sodium Tripolyphosphate				X	
Isopropanol	X	X		X	
Propylene Oxide		X		X	X
Acetic Anhydride		X		X	X
Titanium Dioxide				X	X
Vinyl Acetate		X	X	X	
Sodium Silicate				X	
Acetaldehyde	X	X		X	X
Acrylonitrile		X	X	X	X

The Department of Transportation issues regulations regarding the transportation, packaging for shipment, loading, unloading, and labeling of substances classified as "hazardous materials." The list of materials is under constant review for revision. Ordering of priority attention is paid in considering the possibility of multiple hazards (i. e., flammable plus explosive) and through an assumption that the least expensive chemicals will receive the least care in handling.

The Food and Drug Administration listing is incomplete since it only indicates those substances involved in food additive petitions pending as of June 30, 1974. A thorough index of FDA activities in reference to all chemicals was not feasible to produce at this time.

The National Institute for Occupational Safety and Health has produced the excellent publication, Toxic Substances List 1974, which is being discussed by Dr. Christensen. The listing in the matrix is taken from that volume. The Occupation Safety and Health Administration promulgates regulations setting standards for the workplace based on criteria documents prepared by NIOSH. Those high volume chemicals for which there are existing standards were indicated in Table 3.

Additional data are being sought in amplification and completion of the matrices. An attempt can be made to update the tables at the meetings, if this is desirable.

Monitoring Data

Registers of U.S. toxic substances monitoring data are kept by various Offices within and outside EPA. The data systems currently are being surveyed for content of data on toxic substances. A list of the data systems known or believed to contain toxic chemicals monitoring data is included as Table 4 (below).

The most important of these systems in terms of water data volume is STORET. This system contains raw water quality data stored under a variety of parameter names (dissolved, inorganic suspended, total, etc.) This computerized file may be accessed through teletype link and for less than 3,000 lines of printout the turnover time is approximately 5-24 hours.

The principal air monitoring data file is SAROAD. This system contains a diverse range of parameters including, as examples, heavy metals, halogens, organometallic compounds, and organic substances. The turnaround time for data, including mailing from North Carolina, is two to four days. The System allows for storage of data concerning air quality standards and emissions throughout the United States.

Table 4 -- A Brief List of Known Monitoring Agencies in the United States

USDA

Meat and Poultry Inspection. A National Monitoring Program.

U.S. Army

Hydraulic Engineering Center. A monitoring program.

USDI

Fish and Wildlife Service. Duck wing analyses, Mercury in fish, Pesticide appraisal in Starling, National Water Data System.

USEPA

Estuarine and Coastal monitoring for halogenated hydrocarbons, National Eutrophication Study.

USDHEW

Diet Studies program, shellfish sanitation program.

USDC

Monitoring by NOAA Air Research Labs, Coastal Environment and Marine Ecology, commercial fish pollutants

USTVA

Water Quality, air quality monitoring.

Universities in 13 States

Monitor for various pollutants (Amherst College, University of Arkansas, University of Southern California, University of Hawaii, University of Iowa, Iowa State University, University of Maryland, Massachusetts Institute of Technology, University of New Mexico, New Mexico Institute of Technology, Ohio State University, Oregon State University, University of Rhode Island, University of California, University of Georgia, Texas A&M University, University of Washington, and Woods Hole Oceanographic Institute).

The National Soils Monitoring Program is concerned with the levels of pesticides residue in soils and in croplands. Samples are taken from throughout the U.S. on the basis of one site per 400,000 acres of soil. All samples are processed at a laboratory in St. Louis, Missouri, and most analytical work is done at the same site.

The Technical Assistance Data System is a compilation of records on more than 850 hazardous materials (being expanded) from a variety of sources. A computer provides printouts via remote terminals to furnish the major informational elements required in the control of chemical releases as well as for enforcement and research activities in developing anti-spill programs. Emphasis is on spill characteristics, potential environmental problems with spills, and containment procedures.

The National Pesticides Monitoring Program measures the pesticides levels in water, soils, wildlife, fishes, food, feed and humans. This monitoring takes place throughout the U.S. on an annual basis. All data are sent to the EPA Ecological Monitoring Branch where they are stored in a computer system.

The Interstate Carrier Water Supply Certification Program monitors bacteria and chemicals in water used on interstate carrier systems. Drinking water certification is required annually. Samples are taken by EPA once each year for chemical analysis. About 25 parameters are measured.

No principal data system exists for tissues or animal data, however, several data files are concerned with toxicological information in one form or another.

Priorities Perceived by Congress

Another approach to U.S. interest in toxic substances has been an examination of the substances mentioned in Congressional hearings concerning the Toxic Substances Control Act. Table 5 (below) lists these substances.

Prioritization Procedures

The selection of chemicals for priority attention is a function of any nation seeking to protect its citizens from the adverse effects of toxic substances. Activities within EPA in attempting to set priorities include studies in correlations of properties and/or structure with effects; studies of identification systems for the establishment of priorities; groupings of chemicals within chemical classes; projects in current awareness of problems with chemicals; and various types of consultations and conferences. The ranking of chemicals on a scale of environmental hazard is an important but difficult process.

Table 5 -- List of Chemicals Considered at U.S. Congressional Hearings on the Toxic Substances Control Act

Aluminum
Antibiotics
Arsenic
Asbestos
Beryllium
Boiler Cleaning Products
Cadmium
Cadmium Oxide
Cadmium Sulfide
Carbadox
Carbamate
Carbonates
Carcinogenic Animal Drugs
Chemical Reagents, Catalysts, and Intermediates
Chromium
Chlorinated Hydrocarbons
Chlorinated Paraffins
Chlorine
Chlorodoxins
Chloromadinone Acetate
Copper
Corrosion Inhibitors
Corticosteroids
Cyclamates
DEHP (Diethylhexyl Phthalate)
DDT, 2,4,5-T
Detergents
Dialkyl Esters
Dichlorvas
Diethylstibestrol (DES)
Dimetridazole
Dinestrol Diacetate
Endotoxins
Estradiol Benzoate
Estradiol Monopalmitate
Food Additives
Fungicides
Furaltadone
Furazolidone
Gasoline Additives
Hexobarbitol
Hydrogen Cyanide
Inert Polystyrene
Inks
Ipronidazole
Iron Complexes
Lead
Lead Acetate
Manganese
Medroxyprogesterene Acetate
Melegesterol Acetate
MER-29
Mercury
Methylate
Methyl Mercury
Mutagenic Drugs
Nickel
Nickel Carbonyl
Nihvorazone
Nihydrazone
Nitrofurazone
NTA (Nitrilotriacetic Acid)
Ochratoxin
Organophosphate Esters
PAE's (Phthalic Acid Esters)
Patulin
PCB's
Penicillic Acid
Pesticides
Phosgene
Phosphates
Phthalate Esters
Plating Additives
Polychlorinated Paraffins
Polychlorinated Terpenes
Polymerization Modifiers
Potassium Cyanide
Progesterone
PVC (polymerized vinyl chloride)
Reserpine
Silica
Silicates
Selenium
Sterigmatocystin
Sodium
Teratogenic Drugs
Testosterone
Testosterone Propionate
Thalidomide
Types of Talcs
Vanadium
Zeranol
Zinc
Zinc Sulfide

Aerosols
Alkyl Benzene
Antimony
Arsenic Trioxide
Barium
Caustic Soda
Cyanide
Dyestuffs
Ethyl Fluoracetate
Flame Retardent Chemicals
  octabromodiphenyl oxide
  decabromodiphenyl oxide
Freon Propellants
Herbisan
Hydrocyanic acid
Mercuric salts
Molybdenum
Nickel Carbonyl
ONCB (orthonitrochlorobenzene)
Silver
Sodium Cyanide
Sodium Fluoracetate
Sodium Tripolyphosphates
Tetraethyl Lead
Urethane Foam

Although there is much interest in the establishment of priorities in considerations of decisions involving regulation, research and monitoring for special chemicals, full participation in an international registry would be difficult for the United States. Regulatory agencies are active at different levels of government and with differing goals. The format of the existing information is varied and its quality mixed. There does not exist a management control mechanism where the interest in a registry would have force and continuity. In the absence of a completed system it is easier to obtain the needed data from existing sources.

The idea of an International registry is an interesting one. Its implementation will not be easy.

ROLE OF THE ENVIRONMENTAL PROTECTION AGENCY IN ESTABLISHING STANDARDS ON TRACE CONTAMINANTS

Delivered by
Farley Fisher, Ph.D.

to the
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I do not plan to talk much about the problem of setting standards in the sense that standards use numerical limits, but I do want to discuss the activities in the EPA which are aimed toward the control of contaminants. The EPA clearly is very concerned about trace contaminants, and in fact, the public concern over these materials was the primary impetus for the very creation of the Agency.

Up to the present time, the major thrust within the Agency has been to control certain environmental contaminants, which we will refer to as "media pollutants". For example, we have talked about air pollution, we have identified five or so serious air pollutants, and we are quibbling about whether half a dozen others ought to be considered serious air pollutants. For those we have identified, we've set standards, rather tough standards in some cases, and we've implemented programs to try and meet these standards. We have also been active in the area of water pollutants, where a similar type of problem exists, and with the new water legislation, which gives the Agency considerably more authority to control effluent outfalls, I think one can anticipate that there will be much more activity in the area of controlling trace environmental contaminants in the water as they come out of the industrial process.

I am only peripherally acquainted with the details of the activities going on in the Water and Air Programs. I belong to the Office of Toxic Substances which is a unit created to handle environmental contamination problems which cannot be effectively controlled by these media authorities.

An example of the type of problem which led to the creation of such an Office is the PCB problem, where everybody sat around and said, "Oh, boy, this stuff is all over the place now. We think maybe it's dangerous." But the Air people said, "It very seldom occurs in the air", the Water people said, "Well sometimes it is in water, but in fact there is a very small amount of the population exposed to PCB's." The FDA people said, "Well, it is not a food and is not used as a drug but it does occasionally occur in food packaging, but would be dangerous only in case of a rather dire accident, so it is not a serious concern to us although we will do a little bit about it, too." Now when we got all done, we found that the PCB's were still reaching the environment in large quantities and nobody was really taking on the responsibility for it. At this point an interagency task force was formed which finally decided that something must be done, but the Government had no authority to do anything. We were saved in this impasse by the Monsanto Company which happened to be the only domestic producer of PCB's and which voluntarily instituted controls on the chemical. But the whole problem simply pointed out the fact that this existing piecemeal approach to environment pollution, considering air and water, and really leaving out all other considerations, is not adequate.

In other words, we are leaving ourselves wide open for a lot of problems. In light of this fact, the Agency created the Office of Toxic Substances. To create an office makes it look like we are doing something, but if the office has no authority to do anything, what in the world is it all about? There has been proposed in the last congress a Toxic Substances Control Act. Let me give you an idea of the philosophy behind the so-called "Toxic Substances Control Act." The Toxic Substances Control Act would require testing of any industrial material for which there was a reason to suspect a serious hazard existed with regard either to human health or to general environmental balance. In the event this testing confirms the suspicion, then the government, mainly EPA, will be authorized to restrict its use in a number of ways. In some cases, we could banish these products altogether, but for the most part we are talking in terms of restricting them in any of a number of ways: use in certain geographic areas, in terms of limited quantities which may be used, or in terms of the specific applications to which the material may be applied. Both the Senate and the House in the last session of Congress passed different versions of this Act; they were not able to agree on a version suitable to both houses before adjourning. Consequently, there is no legislation at this point. However, we do anticipate that it will be debated again in the upcoming session of Congress.

There are, it is fair to point out, a couple of legislative authorities in the government not administered by EPA which do bite at the edges of this problem of general environmental contamination. These are, first, the Federal Hazardous Substances Act, designed to protect consumers from direct hazards from products they buy for personal use. This is the authority under which the sale of carbon tetrachloride as a home cleaning fluid was banned. This is also the authority under which various detergent tests are being conducted and some labeling restrictions are being placed on detergents to warn consumers that they may be toxic or corrosive. However, many detergents are not required to carry these warning labels.

The Hazardous Substances Act is really, however, rather limited in its scope to products which are sold for direct use by consumers and which pose a hazard in their direct use or in their storage in the home. It does not cover indirect hazards, and I think an excellent sample of this type of problem is the NTA controversy. The problem with nitrilotriacetic acid is pretty clearly not one of causing death immediately upon exposure, for example, if children should open a box of detergent. The risks involved with

NTA are related to what happens to the material after the clothes are washed and the wash water is flushed down the drain and into the sewer. At what point does the compound enter the environment generally? There are a lot of unanswered questions as to what its fate is in the environment, as to how much it will occur in the water supply, and as to what the ultimate effects will be from repeated low level exposure to this material.

Another authority which has a surprising ability to impact this area is the Occupational Safety and Health Act. This is a law which is designed, of course, to protect workers in an industrial atmosphere. This Act does enable the officials of HEW and Labor acting in concert to propose certain restrictions on these chemicals which are designed for the protection of industrial workers, but which, in many cases, will inevitably have the side effects of also improving the general environment in the neighborhood of industrial plants. And so we can anticipate that this Act, which really was not passed for environmental purposes, may have environmental fallout. Nevertheless, we feel the very strong need for a more direct authority to handle materials on a much more direct scale than is provided by these rather peripheral and tangential types of authority.

These are a couple of basic philosophies that I would like to impart to you regarding EPA thoughts in this area. One is that there is a growing feeling within the Agency that the intelligent and most effective and most economical way to handle problems of environmental contamination is not by add-on devices on the smokestack or the outfall pipe, but rather by looking more closely at what is really going on inside the plant and seeing what we can do to prevent the production of a pollutant in the first place.

We also feel that there are many toxic products which can be safely used, including many industrial and intermediate type products. I'm speaking now of products which can be safely used in an environmental sense, not in terms of occupational problems. In looking back at problems that have been of concern up to the present time, it seems that by being a little more careful about how we can do things, we can probably avoid a lot of problems which we are now getting into. A good example is mercury contamination of our waterways; it is largely just a result of poor housekeeping on the part of certain industries.

Undoubtedly there will be some materials that we are going to find are impossible toxic substances and that we are going to have to abandon eventually. This may mean in some cases giving up certain conveniences we now have, although probably not to any great extent.

We are quite concerned with evaluating potential substitutes for toxic materials. We are also very concerned with the problem of trying to create an economic situation where a manufacturer will find it to his benefit to use a safe alternative to a dangerous raw material even though it may cost him a penny or two a pound more.

And finally there is a need for better industrial processes so that we can produce some of the products that we use and enjoy in this country and eliminate some of the contaminants which are present in these products and are causing us all kinds of problems. One thing that comes to mind in this regard is the prevalence of dioxin in 2,4,5-T. It is generally felt that the dioxin is a general environmental threat much more severe than the herbicide itself. If we could make 2,4,5-T which is free of dioxin, the Agency would feel much better about continuing its use as a herbicide. Do not read into that any implication that the Agency has made a decision on 2,4,5-T, because it has not.

Another example is the problem of cadmium which may be contained in zinc. Many people feel that cadmium is a serious environmental pollutant. There are considerable data to substantiate the fact that cadmium has severe adverse health effects even at relatively low concentration. It's ores occur with those of zinc, and one of the principal routes of entry of cadmium into the environment comes from the fact that cadmium is entrained with zinc in existing metallurgical processes.

Both the legislation and the operating philosophy of the Office realize that there are other considerations besides direct health and ecological considerations. Nevertheless we consider the health and ecological considerations to be of primary importance if for no other reason that if there is no health or ecological threat from the material, there is no reason for us to worry about it and look at the other aspects that need to be considered.

But there are economic factors which come into play in various ways. We do have to worry about creating large-scale unemployment. We do have to worry about large-scale disruption of the lifestyle or the economy, which of course, would occur if we started to ban large numbers of chemical products on a wholesale basis.

We are worried very much about an abstract being which we refer to as "social utility" which is very close to the quality of life factor which is often mentioned. I know you appreciate that there are many things which have a convenience or an aesthetic or a general humanitarian value which our society recognizes as far in excess of any economic value we put on the product. An example often cited to the Agency is the use of DDT for malaria control. The economic impact of its use is probably minimal, yet most people recognize the social impact could be great.

We have to worry very much about the state of technology. It is very nice for us to say that you shall make 2,4,5-T without dioxin. But if that can't be done, this is tantamount to saying that you shall not make 2,4,5-T.

We have to worry about what alternatives are available. If you go out and say that 2,4,5-T is dangerous, everybody says, "Fine, I won't use 2,4,5-T, I'll use ________," and we do not yet know whether _______ is dangerous. We may be jumping from the frying pan into the fire.

These are all very important considerations of which we are aware.

There is one more point I want to make. I want to address the question. "Exactly what is the government going to do in order to solve all these problems for industry?" I have a very unpleasant answer for you. The government is not going to do very much. Basically, it is the philosophy in the EPA that the costs of testing products and costs of ameliorating the risks imposed on society by products should be borne by the persons who derive the benefit and not by the public at large. The way to accomplish this is to require that the costs of testing, of control, of design modifications, or whatever else is necessary to ameliorate the difficulty should be borne by the industry producing the product, with the general assumption that this industry will, in the normal course of business, pass these costs on to its customers. The government should not get into the business of spending tax dollars to develop industrial process or control technology except in very exceptional cases.